Indiana Pharmacy Laws and Regulations

A Compilation of Indiana Code and Indiana Administrative Code

2002 Edition

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For questions about federal law and regulations pertaining to drugs and the practice of pharmacy, contact the nearest office of the U.S. Food and Drug Administration (FDA) or the U.S. Drug Enforcement Administration (DEA).

IC 25-26-13

Chapter 13. Regulation of Pharmacists and Pharmacies.

Creation of Board

IC 25-26-13-1

Sec. 1. The practice of pharmacy is declared to be a professional occupation in the state of Indiana, affecting the public health, safety, and welfare and must be subject to regulation and control in the public interest by the board of pharmacy. It is further declared to be a matter of public interest and concern that the practice of pharmacy merit and receive the confidence of the public and that only qualified persons be permitted to practice pharmacy in the state of Indiana.
As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-1.5

Sec. 1.5. A right or benefit accrued under IC 25-26-1 through IC 25-26-12 before July 1, 1977, is continued under this chapter.
As added by P.L.1-1989, SEC.52.

IC 25-26-13-2a

Note: This version of section amended by P.L.270-2001, SEC.2. See also following version of this section amended by P.L.288-2001, SEC.1.

Sec. 2. As used in this chapter:

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the Federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, invitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purpose through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" means a physician licensed under IC 25-22.5, a veterinarian licensed under IC 15-5-1.1, a dentist licensed under IC 25-14, a podiatrist licensed under IC 25-29, or any other person licensed by law to prescribe and administer legend drugs in this state.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist extern" means a pharmacy student enrolled full-time in an approved school of pharmacy and who is working in a school sponsored, board approved program related to the practice of pharmacy.

"Pharmacist intern" means a person who is working to secure additional hours of practice and experience prior to making application for a license to practice as a pharmacist.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern, a pharmacist extern, or an unlicensed person under section 18(a)(4) of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order, or sold or

given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user for any drug or device containing the name and address of the patient, the name and strength or size of the drug or device, the amount to be dispensed, adequate directions for the proper use of the drug or device by the patient, and the name of the practitioner issued and, if the prescription is in written form, signed by a practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.149-1987, SEC.72; P.L.2-1993, SEC.144; P.L.187-1999, SEC.1; P.L.270-2001, SEC.2.

Note: See also following version of this section amended by P.L.288-2001, SEC.1.

IC 25-26-13-2b

Note: This version of section amended by P.L.288-2001, SEC.1. See also preceding version of this section amended by P.L.270-2001, SEC.2.

Sec. 2. As used in this chapter:

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the Federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist extern" means a pharmacy student enrolled full-time in an approved school of pharmacy and who is working in a school sponsored, board approved program related to the practice of pharmacy.

"Pharmacist intern" means a person who is working to secure additional hours of practice and experience prior to making application for a license to practice as a pharmacist.

"Pharmacy" means any facility , department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern, a pharmacist extern, or an unlicensed person under section 18(a)(4) of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order, or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) the signature of the practitioner if the prescription is in written form.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.149-1987, SEC.72; P.L.2-1993, SEC.144; P.L.187-1999, SEC.1; P.L.288-2001, SEC.1.

Note: See also preceding version of this section amended by P.L.270-2001, SEC.2.

IC 25-26-13-3

Sec. 3. (a) The Indiana board of pharmacy is created. It shall consist of seven (7) members not more than four (4) of whom may be from the same political party, appointed by the governor for terms of four (4) years. One (1) member of the board, to represent the general public, must be a resident of this state who has never been associated with pharmacy in any way other than as a consumer. Except for the member representing the general public, the members must be pharmacists in good standing of recognized experience and ability from varied practice settings who hold a current license to practice pharmacy in Indiana. One (1) member of the board must be a practicing hospital pharmacist. A person employed as a full-time staff member or as a professor at a school of pharmacy may not serve on the board. If a member leaves the board for any reason before the end of the member's term, the member's successor shall serve for the unexpired portion of the term.

(b) Not later than ten (10) days after a member's appointment, the member must subscribe by oath or affirmation to faithfully uphold the duties of the member's office. If a member fails to qualify as provided, a new member shall be appointed in the member's place.

(c) At the first meeting of each year the board shall elect from among its members a president and vice president who shall perform duties and have powers as the board prescribes.

(d) The board shall meet at least eight (8) times per year at such times and places as the board selects. At each meeting the board shall continue in session from day to day, for not more than five (5) days, until the business of the meeting is complete. Four (4) members of the board shall constitute a quorum.

(e) Each member of the board is entitled to compensation as determined by the rules of the budget agency for each day the member is actually engaged in business of the board, together with necessary travel and other expenses incurred in the performance of the member's duties.

(f) Approval by a majority of the quorum is required for any action to be taken by the board.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.185; P.L.157-1986, SEC.1; P.L.48-1991, SEC.45; P.L.187-1999, SEC.2.

IC 25-26-13-4

Sec. 4. (a) The board may:

(1) promulgate rules and regulations under IC 4-22-2 for implementing and enforcing this chapter;

(2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists' licenses;

(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;

(4) regulate the sale of drugs and devices in the state of Indiana;

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; and

(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(c) The board may grant or deny a temporary variance to a rule it has adopted if:

(1) the board has adopted rules which set forth the procedures and standards governing the grant or denial of a temporary variance; and

(2) the board sets forth in writing the reasons for a grant or denial of a temporary variance.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.186; P.L.75-1992, SEC.20; P.L.2-1993, SEC.145; P.L.177-1997, SEC.5.

IC 25-26-13-4.5

Sec. 4.5. (a) As used in this section, "impaired pharmacist" means a licensed pharmacist who has been affected by the use or abuse of alcohol or other drugs.

(b) The board shall assist in the rehabilitation of an impaired or a licensed pharmacist. The board may:

(1) enter into agreements, provide grants, and make other arrangements with statewide nonprofit professional associations or foundations to identify and assist impaired pharmacists or licensed pharmacists; and

(2) accept and designate grants, public and private financial assistance, and licensure fees to fund programs under subdivision (1).

(c) Except as provided in subsection (e), all:

(1) information furnished to a nonprofit professional organization or foundation, including interviews, reports, statements, and memoranda; and

(2) findings, conclusions, or recommendations that result from a proceeding of a professional organization or foundation;

are privileged and confidential.

(d) The records of a proceeding under subsection (c) may be used only in the exercise of the proper functions of the board and may not become public records or be subject to a subpoena or discovery proceeding.

(e) Information received by the board from the board designated rehabilitation program for noncompliance by the licensed pharmacist may be used by the board in any disciplinary or criminal proceedings instituted against the impaired licensed pharmacist. (f) The board designated rehabilitation program shall:

(1) immediately report to the board the name and results of any contact or investigation concerning an impaired licensed pharmacist that the program believes constitutes an imminent danger to either the public or the impaired licensed pharmacist; and

(2) in a timely fashion report to the board an impaired licensed pharmacist:

(A) who refuses to cooperate with the program;

(B) who refuses to submit to treatment; or

(C) whose impairment is not substantially alleviated through treatment.

As added by P.L.188-1995, SEC.4.

IC 25-26-13-5

Sec. 5. (a) The executive director shall keep a record of the proceedings of the board. The record shall contain the names and addresses of all persons who apply to the board for a license or permit and the action taken on each.

(b) The board shall hire and supervise a sufficient number of inspector-investigators to enforce the controlled substances law (IC 35-48). Inspector-investigators hired by the board are employees of the health professions bureau.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.187; Acts 1982, P.L.113, SEC.64; P.L.169-1985, SEC.87.

IC 25-26-13-6

Sec. 6. The board may accept and expend funds from sources other than the state of Indiana, provided that:

(1) such funds are awarded for the pursuit of a specific objective which the board is authorized to accomplish by this chapter, or which the board is qualified to accomplish by reason of its jurisdiction or professional expertise;

(2) such funds are expended for the pursuit of the objective for which they are awarded;

(3) activities connected with or occasioned by the expenditures of such funds do not interfere with or impair the performance of the board's duties and responsibilities and do not conflict with the exercise of the board's powers as specified by this chapter;

(4) such funds are kept in a separate, special account in the state treasury; and

(5) periodic reports are made to the governor concerning the board's receipt and expenditure of such funds.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-7

Sec. 7. With respect to pharmacists, pharmacies, drugs, controlled drugs, legend drugs, and devices and the enforcement of this chapter, the board shall have the same powers, duties, and functions as specified in IC 16-42-20-2. *As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.2-1993, SEC.146.*

IC 25-26-13-8

Sec. 8. (a) Not later than October 31 of each odd-numbered year, a form for application for renewal of a pharmacy permit shall be sent to each permit holder, together with a bill for fees due.

(b) Not later than April 30 of each even-numbered year, a form for application for renewal of a pharmacist's license shall be sent to each license holder, together with a bill for fees due.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.188.

IC 25-26-13-9

Sec. 9. (a) The board shall establish standards for pharmacist intern and pharmacist extern programs. Such standards shall include, but not be limited to, the number of hours students must spend in a program, the number of hours a student must spend in a pharmacy each week, and the types of duties the student may perform.

(b) The board shall, by regulation, establish standards and requirements for continuing education and shall endorse those continuing education programs which meet the standards and requirements.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-10

Sec. 10. (a) An applicant for registration as a pharmacist intern or pharmacist extern must furnish proof satisfactory to the board that the applicant is a high school graduate or its equivalent, has obtained a general educational development (GED) diploma, or is enrolled in a pre-pharmacy or pharmacy curriculum at an accredited school of pharmacy. The board may require the applicant to successfully complete an examination prior to registering the applicant as a pharmacist intern or pharmacist extern.

(b) A registration issued under subsection (a) of this section is valid for six (6) years from the date of issuance and may be renewed by the board for an additional five (5) years for good cause shown.

(c) An application for registration or renewal must be accompanied by the appropriate fee.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.187-1999, SEC.3.

IC 25-26-13-11

Sec. 11. (a) To be eligible for licensure as a pharmacist, an individual must file such evidence as is required by the board that:

(1) the individual is at least eighteen (18) years of age;

(2) the individual does not have a conviction for a crime that has a direct bearing on the individual's ability to practice competently;

(3) the individual:

(A) has graduated with a professional degree from a school of pharmacy accredited by the American Council of Pharmaceutical Education or the Canadian Council on Pharmacy Accreditation and approved by the board; or

(B) has:

(i) graduated with a professional degree from a school of pharmacy located outside the United States and Canada; and

(ii) met the requirements under subsection (c); and

(4) the individual has satisfactorily completed either a pharmacist intern or pharmacist extern program approved by the board.

(b) An applicant who has graduated with a professional degree from a school of pharmacy accredited by the Canadian Council on Pharmacy Accreditation and approved by the board must pass the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) administered by the National Association of Boards of Pharmacy before taking the examination required under subsection (d).

(c) An applicant who has graduated with a professional degree from a school of pharmacy located outside the United States and Canada must do the following:

(1) Provide the board with verification of the applicant's academic record and graduation.

(2) Pass the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) administered by the National Association of Boards of Pharmacy.

(3) Pass an examination approved by the board to establish proficiency in English.

(d) After filing an application on a form provided by the board, submitting the information required in subsection (a), and successfully completing the examination administered by the board, the applicant may be licensed as a pharmacist.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.189; Acts 1982, P.L.113, SEC.65; P.L.169-1985, SEC.88; P.L.149-1987, SEC.73; P.L.152-1988, SEC.21; P.L.48-1991, SEC.46; P.L.33-1993, SEC.44; P.L.242-1995, SEC.2.

IC 25-26-13-12

Sec. 12. (a) An individual who is licensed as a pharmacist in another state where the requirements for licensure were not less than those required in this state at the time of original licensure may be issued a license in this state if:

(1) the individual has registered with and been approved by the National Association of Boards of Pharmacy;

(2) the individual has graduated with a professional degree in pharmacy from a school of pharmacy accredited by the American Council of Pharmaceutical Education or the Canadian Council on Pharmacy Accreditation and approved by the board;

(3) the individual has successfully completed an examination administered by the board concerning the federal statutes and regulations and the Indiana statutes and rules governing the practice of pharmacy; and

(4) in the case of an individual who has not been actively engaged in the practice of pharmacy for the twelve (12) months immediately preceding the individual's application, the individual has successfully completed a practical examination administered by the board.

(b) An individual who has a professional pharmacy degree from a school of pharmacy located outside the United States and Canada and who is licensed in another state where the requirements for licensure are substantially the same as those in this state may be issued a license under this chapter if:

(1) the individual has registered with and been approved by the National Association of Boards of Pharmacy;

(2) the individual has provided the board with proof of the applicant's:

(A) academic record and graduation with a professional degree from a school of pharmacy;

(B) successful completion of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) approved by the National Association of Boards of Pharmacy; and

(C) successful completion of an English proficiency examination approved by the board;

(3) the individual has successfully completed an examination administered by the board concerning the federal statutes and regulations and the Indiana statutes and rules governing the practice of pharmacy; and

(4) in the event that the individual has not been actively engaged in the practice of pharmacy in the twelve (12) months preceding the application, the individual has successfully completed a practical examination administered by the board.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.169-1985, SEC.89; P.L.156-1986, SEC.2; P.L.149-1987, SEC.74; P.L.33-1993, SEC.45; P.L.242-1995, SEC.3; P.L.288-2001, SEC.2.

IC 25-26-13-12.5

YAMD.1995

Sec. 12.5. (a) The board may issue a temporary license to an individual who:

(1) applies to the board for a license; and

(2) meets all requirements of section 12 of this chapter except for completing the examination under section 12(b)(2)(B) of this chapter.

(b) The temporary license issued under this section:

(1) shall remain in effect until the individual receives the results of the first examination completed by the individual under section 12(b)(2)(B) of this chapter; and

(2) may not remain in effect for more than twelve (12) months.

(c) The board shall adopt rules under IC 4-22-2 to implement this section.

As added by P.L.242-1995, SEC.4.

IC 25-26-13-13

Sec. 13. (a) A person holding a pharmacist license shall be considered an active pharmacist if his fees are current and he has complied with all continuing education requirements.

(b) Any active pharmacist either by his own choice or by action of the board after hearing, may be classified as an inactive pharmacist. An inactive pharmacist may maintain his license by paying his license fees. An inactive pharmacist is exempt from the continuing education requirements. A person may not actively engage in the practice of pharmacy while classified as an inactive pharmacist.

(c) A person classified as an inactive pharmacist may reactivate his license by meeting current continuing education requirements and successfully demonstrating to the board's satisfaction his ability to actively practice as a pharmacist.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-14

Sec. 14. (a) A pharmacist's license expires July 1 of each even-numbered year, unless renewed before that date.

(b) If an application for renewal is not filed and the required fee paid before July 1 of each even-numbered year, the license expires and becomes invalid, and may be reinstated only by meeting the requirements under IC 25-1-8-6.

(c) Subject to IC 25-1-4-3, a statement attesting that the pharmacist

has met the continuing education requirements shall be submitted with the application for license renewal.

(d) If a pharmacist surrenders the pharmacist's license to practice pharmacy in Indiana, the board may subsequently consider reinstatement of the pharmacist's license upon written request of the pharmacist. The board may impose any conditions it considers appropriate to the surrender or to the reinstatement of a surrendered license. The practitioner may not voluntarily surrender the practitioner's license to the board without the written consent of the board if any disciplinary proceedings are pending against the practitioner under this chapter or IC 25-1-9.

(e) If a person fails to renew a license that expires under subsection (a) within three (3) years after the date the license expires, the board may reinstate the license only if the person:

(1) meets the requirements under IC 25-1-8-6; and

(2) passes an examination concerning state and federal laws that the board considers relevant to the practice of pharmacy.

(f) The board may require a person who applies for a license under subsection (e) to appear before the board and explain the reason the person failed to renew the person's license.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.190; P.L.169-1985, SEC.90; P.L.149-1987, SEC.75; P.L.48-1991, SEC.47; P.L.269-2001, SEC.25.

IC 25-26-13-15

IC 25-26-13-15 Sec. 15. (a) A pharmacist shall hold in strictest confidence all prescriptions, drug orders, records, and patient information. He may divulge such information only when it is in the best interest of the patient or when requested by the board or its representatives or by a law enforcement officer charged with the enforcement of laws pertaining to drugs or devices or the practice of pharmacy.

(b) A person who has knowledge by virtue of his office of any prescription drug order, record, or patient information may not divulge such information except in connection with a criminal prosecution or proceeding or a proceeding before the board, to which the person to whom the information relates is a party.

(c) A pharmacist or pharmacy is immune from civil liability for any action based on its good faith release of information under this section.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-16

Sec. 16. (a) A pharmacist shall exercise his professional judgment in the best interest of the patient's health when engaging in the practice of pharmacy.

(b) A pharmacist has a duty to honor all prescriptions from a practitioner or from a physician, podiatrist, dentist, or veterinarian licensed under the laws of another state. Before honoring a prescription, the pharmacist shall take reasonable steps to determine whether the prescription has been issued in compliance with the laws of the state where it originated. The pharmacist is immune from criminal prosecution or civil liability if he, in good faith, refuses to honor a prescription because, in his professional judgment, the honoring of the prescription would:

(1) be contrary to law;

(2) be against the best interest of the patient;

(3) aid or abet an addiction or habit; or

(4) be contrary to the health and safety of the patient.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.156-1986, SEC.3.

IC 25-26-13-16.5

Sec. 16.5. Pharmacists licensed by Indiana may fill prescriptions of optometrists who are:

(1) licensed by Indiana; and

(2) certified under IC 25-26-15;

for a drug that is included in the formulary adopted under IC 25-26-15-13.

As added by P.L.147-1991, SEC.3.

IC 25-26-13-17

Sec. 17. (a) The board shall establish classes of pharmacy permits as follows:

Type I. A retail permit for a pharmacy that provides pharmaceutical care to the general public by the dispensing of a drug or device.

Type II. An institutional permit for hospitals, clinics, health care facilities, sanitariums, nursing homes, or dispensaries that offer pharmaceutical care by dispensing a drug product to an inpatient under a drug order or to an outpatient of the institution under a prescription.

Type III. A permit for a pharmacy that is not:

(A) open to the general public; or

(B) located in an institution listed under a Type II permit;

and provides pharmaceutical care to a patient who is located in an institution or in the patient's home.

Type IV. A permit for a pharmacy not open to the general public that provides pharmaceutical care by dispensing drugs and devices to patients exclusively through the United States Postal Services or other parcel delivery service.

Type V. A permit for a pharmacy that engages exclusively in the preparation and dispensing of diagnostic or therapeutic radioactive drugs.

Type VI. A permit for a pharmacy open to the general public that provides pharmaceutical care by engaging in an activity under a Type I or Type III permit. A pharmacy that obtains a Type VI permit may provide services to:

(A) a home health care patient;

(B) a long term care facility; or

(C) a member of the general public.

(b) Hospitals holding a Type II permit may offer drugs or devices to an employee, student, or medical staff member or their dependents for their own use.

(c) Nothing in this section prohibits a pharmacy holding a permit other than a Type IV permit from delivering drugs or devices through mail, parcel delivery, or hand delivery.

(d) Any applicable rule governing the practice of pharmacy in Indiana shall apply to all permits under this section.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.149-1987, SEC.76; P.L.147-1991, SEC.4.

IC 25-26-13-18

Sec. 18. (a) To be eligible for issuance of a pharmacy permit, an applicant must show to the satisfaction of the board that:

(1) Persons at the location will engage in the bona fide practice of pharmacy. The application must show the number of hours each week, if any, that the pharmacy will be open to the general public.

(2) The pharmacy will maintain a sufficient stock of emergency and frequently prescribed drugs and devices as to adequately serve and protect the public health.

(3) Except as provided in section 19 of this chapter, a registered pharmacist will be in personal attendance and on duty in the licensed premises at all times when the practice of pharmacy is being conducted and that the pharmacist will be responsible for the lawful conduct of the pharmacy.

(4) One (1) pharmacist will have not more than four (4) unlicensed persons under the pharmacist's immediate and personal supervision at any time. As used in this clause, "immediate and personal supervision" means within reasonable visual and vocal distance of the licensed person.

(5) The pharmacy will be located separate and apart from any area containing merchandise not offered for sale under the pharmacy permit. The pharmacy will:

(A) be stationary;

(B) be sufficiently secure, either through electronic or physical

means, or a combination of both, to protect the products contained in the pharmacy and to detect and deter entry during those times when the pharmacy is closed;

(C) be well lighted and ventilated with clean and sanitary surroundings;

(D) be equipped with a sink with hot and cold running water or some means for heating water, a proper sewage outlet, and refrigeration;

(E) have a prescription filling area of sufficient size to permit the practice of pharmacy as practiced at that particular pharmacy; and

(F) have such additional fixtures, facilities, and equipment as the board requires to enable it to operate properly as a pharmacy in compliance with federal and state laws and regulations governing pharmacies.

A pharmacy licensed under IC 25-26-10 (before its repeal on July 1, 1977) on June 30, 1977, must comply with the provisions of this clause before December 31, 1982, unless for good cause shown the board grants a waiver or otherwise exempts it.

(b) Prior to opening a pharmacy after receipt of a pharmacy permit, the permit holder shall submit the premises to a qualifying inspection by a representative of the board and shall present a physical inventory of the drug and all other items in the inventory on the premises.

(c) At all times, the wholesale value of the drug inventory on the licensed items must be at least ten percent (10%) of the wholesale value of the items in the licensed area.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.3-1990, SEC.90; P.L.27-1998, SEC.1; P.L.187-1999, SEC.4.

IC 25-26-13-19

Sec. 19. (a) A pharmacy holding a Type I or Type VI permit may be open to the general public without a pharmacist on duty if the following conditions are met:

(1) Approval is obtained from the board.

(2) All legend drugs and other merchandise that can only be dispensed by a pharmacist are securely locked or secured by an alternative system approved by the board when the pharmacist is absent.

(3) During the pharmacist's absence, a sign at least twenty (20) inches by thirty (30) inches is prominently displayed in the prescription department stating: "Prescription Department Closed, No Pharmacist on Duty".

(4) Only a pharmacist has access to the secured area.

(b) The board may revoke or limit a pharmacy's privilege under this section after a hearing under IC 4-21.5-3.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.7-1987, SEC.125; P.L.147-1991, SEC.5; P.L.288-2001, SEC.3.

IC 25-26-13-20

Sec. 20. (a) A person desiring to open, establish, operate, or maintain a pharmacy shall apply to the board for a pharmacy permit on a form provided by the board. The applicant shall set forth:

(1) the name and occupation of the persons desiring the permit;

(2) the location, including street address and city, of the pharmacy;

(3) the name of the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operation of the pharmacy under the permit; and

(4) such other information as the board may require.

(b) If the applicant desires to open, establish, operate, or maintain more than one (1) pharmacy, he must file a separate application for each. Each pharmacy must be qualified by a different pharmacist.

(c) The board shall permit a pharmacist to serve as a qualifying pharmacist for more than one (1) pharmacy holding a type II pharmacy permit upon the holder of the type II permit showing circumstances establishing that:

(1) the permit holder has made a reasonable effort, without success, to obtain a qualifying pharmacist who is not serving as a qualifying pharmacist at another type II pharmacy; and

(2) the single pharmacist could effectively fulfill all duties and responsibilities of the qualifying pharmacist at both locations.

(d) The board shall grant or deny an application for a permit not later than one hundred twenty (120) days after the application and any additional information required by the board are submitted.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.169-1985, SEC.91; P.L.270-2001, SEC.3.

IC 25-26-13-21

Sec. 21. (a) A pharmacy permit is not transferable as to location or ownership.

(b) Not later than ten (10) days after the change of ownership of a pharmacy, an application shall be submitted for transfer of ownership accompanied by a signed and dated certificate of sale. The original permit remains valid until a new permit is issued or the application is rejected by the board. Not later than ten (10) days after notice of the board's action, the old permit is void and must be returned immediately by the new owner.

(c) If the holder of a pharmacy permit desires to change the location of the pharmacy, he shall file an application on a form provided by the board for a permit for the new location.

(d) All applications for transfers of ownership or location of a pharmacy must be accompanied by the appropriate fee.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.191.

IC 25-26-13-22

Sec. 22. (a) A pharmacy permit shall expire on December 31 of the odd-numbered year next succeeding the date of issuance.

(b) If an application for renewal has not been filed and the required fee paid by January 1 following the date of expiration, the pharmacy permit shall lapse and may be reinstated only by paying the lapsed permit fee and the appropriate permit fee.

(c) No pharmacy may be open for business, after December 31 of the renewal year, until the renewal is perfected.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.192; P.L.169-1985, SEC.92.

IC 25-26-13-23

Sec. 23. (a) The board shall establish appropriate fees to carry out this chapter.

(b) All fees are nonrefundable. A receipt shall be issued for all fees and fines submitted.

(c) All fees collected under this section and fines collected under IC 25-1-9 shall be transferred to the treasurer of state and deposited in the general fund of the state.

(d) The board may adopt rules that provide that at the time of license renewal, each licensed pharmacist pay an additional fee not to exceed ten dollars ($10). The amounts collected under this subsection shall be deposited in the impaired pharmacists account established under section 30 of this chapter.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.193; P.L.169-1985, SEC.93; P.L.152-1988, SEC.22; P.L.188-1995, SEC.5.

IC 25-26-13-24

Sec. 24. The pharmacy permit and the licenses of the pharmacists primarily employed in the pharmacy shall be prominently displayed in an area where customers at the prescription counter can readily see them.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-25a

Note: This version of section amended by P.L.270-2001, SEC.4. See also following version of this section amended by P.L.288-2001, SEC.4.

Sec. 25. (a) All original prescriptions, whether in written or electronic

format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) Except as provided in subsection (c) before the expiration of subsection (c) on June 30, 2003, a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (f).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (d).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill". This subsection expires June 30, 2003.

(d) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(e) The original prescription form or the other board approved record described in subsection (d) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(f) A prescription is valid for not more than one (1) year after the original date of filling.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient residing in an institutional facility (as defined in 856 IAC 1-28-1(a));

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as defined in IC 25-26-13-17).

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under subsection (h).

(k) A pharmacist who violates subsection (c) commits a Class A infraction.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.239-1989, SEC.1; P.L.33-1993, SEC.46; P.L.188-1995, SEC.6; P.L.187-1999, SEC.5; P.L.270-2001, SEC.4.

Note: See also following version of this section amended by P.L.288-2001, SEC.4.

IC 25-26-13-25b

Note: This version of section amended by P.L.288-2001, SEC.4. See also preceding version of this section amended by P.L.270-2001, SEC.4.

Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than

writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) A prescription for any drug, the label of which bears the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) The refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(d) The original prescription form or the other board approved record described in subsection (c) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(e) A prescription is valid for not more than one (1) year after the original date of issue.

(f) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(h) A pharmacist or a pharmacy shall not accept medication that is returned for resale or redistribution unless the medication:

(1) was dispensed to a patient residing in an institutional facility (as defined in 856 IAC 1-28-1(a));

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as defined in IC 25-26-13-17).

(i) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under subsection (h).

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.239-1989, SEC.1; P.L.33-1993, SEC.46; P.L.188-1995, SEC.6; P.L.187-1999, SEC.5; P.L.288-2001, SEC.4.

Note: See also preceding version of this section amended by P.L.2704-2001, SEC.4.

IC 25-26-13-26

(*Repealed by Acts 1981, P.L.222, SEC.296.)*

IC 25-26-13-26.1

(*Repealed by P.L.152-1988, SEC.30.)*

IC 25-26-13-27

Sec. 27. (a) If a pharmacy will be closed for five (5) consecutive days or more, the permit holder shall notify the board and take such steps to secure the drugs in the pharmacy as the board may direct.

(b) If a pharmacy is to be permanently closed for any reason, the owner or qualifying pharmacist shall:

(1) notify the board not less than twenty (20) days before the transfer of any controlled substances and submit a copy of the inventory form required by the federal drug enforcement administration together with the name, address, and registration number of the person to whom the drugs will be transferred;

(2) remove all legend drugs from stock by:

(A) returning them to the wholesaler or manufacturer if he consents;

(B) transferring them to another pharmacy; or

(C) destroying them in the presence of a representative appointed by the board;

(3) before disposing of any other merchandise in the pharmacy, dispose of all controlled drugs and legend drugs as provided in clauses (1) and (2) and submit the licensed premises to an inspection by a representative of the board to certify that all legend and controlled drugs have been removed;

(4) remove from inside and outside the licensed area all symbols and signs using the words "drugs", "drugstore", "prescriptions", "pharmacy", "pharmacy department", "apothecary", or "apothecary shop", or any combination of such titles; and

(5) return the pharmacy permit for cancellation by the board within ten (10) days after all legend drugs, controlled drugs, drugs and devices are removed from the premises.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.147-1991, SEC.6.

IC 25-26-13-28

Sec. 28. At the request of the board, the attorney general in the name of the state shall apply for an injunction in the circuit court of the county wherein a violation of this chapter is occurring.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-29

Sec. 29. (a) It is unlawful:

(1) For any person to display or permit to be displayed, a pharmacy permit in any facility or place of business other than that for which it was issued.

(2) For any person to accept a prescription for filling or compounding at any place or facility for which there is not a valid pharmacy permit.

(3) For any person to operate a pharmacy or to take, assume, exhibit, display, or advertise by any medium, the title "drugs", "prescriptions", "medicine", "drug store", "pharmacy", or "apothecary shop", or any combination of such titles or any other title, symbol, term, or description of like import intended to cause the public to believe that it is a pharmacy unless he holds a valid pharmacy permit.

(4) For any person to engage or offer to engage in the practice of pharmacy or to hold himself out as a pharmacist without a valid pharmacist's license that is classified as active by the board.

(b) A person who violates a provision of subsection (a) of this section commits a Class D felony.

(c) Nothing in this chapter shall apply to, nor in any manner interfere with the business of a general merchant in selling and distributing nonnarcotic, nonprescription medicines or drugs which are prepackaged, fully prepared by the manufacturer for use by the consumer, and labeled in accordance with the requirements of the state and federal food and drug acts.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-30

Sec. 30. (a) The impaired pharmacists account is established within the state general fund to provide money for the rehabilitation of impaired pharmacists under this article. The account shall be administered by the health professions bureau.

(b) Expenses of administering the account shall be paid from money

in the account. The account consists of money collected under section 4.5(b) of this chapter.

(c) The treasurer of state shall invest the money in the account not currently needed to meet the obligations of the account in the same manner as other public money may be invested. Money remaining in the account at the end of a state fiscal year does not revert to the state general fund.

(d) There is appropriated to the board from the account an amount sufficient to carry out the purpose described in subsection (a).

As added by P.L.188-1995, SEC.7.

IC 25-26-13-31

Sec. 31. (a) A pharmacist may do the following:

(1) Obtain and maintain patient drug histories and other pharmacy records that are related to drug or device therapies.

(2) Perform drug evaluation, drug utilization review, and drug regimen review.

(3) Participate in the selection, storage, and distribution of drugs, dietary supplements, and devices. However, drug selection must comply with IC 16-42-19 and IC 16-42-22.

(4) Participate in drug or drug related research.

(b) A pharmacist who participates in an activity allowed under subsection (a) is required to follow the standards for the competent practice of pharmacy adopted by the board.

As added by P.L.187-1999, SEC.6.

(end of section)

TITLE 856 INDIANA BOARD OF PHARMACY

ARTICLE 1. PHARMACIES AND PHARMACISTS

Rule 1. Application Requirements (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 1.1. Definitions

856 IAC 1-1.1-1 Adoption of definitions
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2; IC 35-48-1-1

Sec. 1. All terms which are defined in IC 25-26-13-2 shall have the same meanings as they are so defined when used in the rules and regulations of the Indiana board of pharmacy found in Article 1 of Title 856 of the Indiana Administrative Code. (Indiana Board of Pharmacy; 856 IAC 1-1.1-1; filed Dec 3, 1985, 3:02 pm: 9 IR 767)

856 IAC 1-1.1-2 "Pharmacy Practice Act" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. The term "Pharmacy Practice Act" when used in these regulations is in reference to Acts 1977, Public Law codified at IC 25-26-13 as amended from time to time. (Indiana Board of Pharmacy; 856 IAC 1-1.1-2; filed Dec 3, 1985, 3:02 pm: 9 IR 767)

856 IAC 1-1.1-3 "In personal attendance" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 3. The term "in personal attendance" as the same is in IC 25-26-13-18(a) of the Pharmacy Practice Act means being physically present in the area specified as the dimensions of the pharmacy in the relevant pharmacy permit application. (Indiana Board of Pharmacy; 856 IAC 1-1.1-3; filed Dec 3, 1985, 3:02 pm: 9 IR 767)

Rule 2. Pharmacists' Certificate

856 IAC 1-2-1 Display of certificate
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 1. Certificates of licensure shall be conspicuously displayed in the drugstore, pharmacy, hospital, dispensary or other place where drugs are sold or dispensed and where the owner or holder thereof is in employment. Failure to comply with this rule shall be deemed sufficient cause for suspension or revocation of the license. (Indiana Board of Pharmacy; Reg 2,Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)

856 IAC 1-2-2 Illegal display of certificate; prohibition
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. The display of a certificate of licensure as a pharmacist in a drugstore, pharmacy, hospital, dispensary, or other place where drugs are sold or dispensed, and in which place the owner and holder of such license is not in bona fide employment, shall be deemed an illegal use of such license, and upon satisfactory proof of such illegal use, such license may be revoked. (Indiana Board of Pharmacy; Reg 2,Sec 2; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)

856 IAC 1-2-3 Notification of address change
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 3. All holders of a license as a pharmacist shall notify the Indiana board of pharmacy of any change of address. (Indiana Board of Pharmacy; Reg 2,Sec 3; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)

856 IAC 1-2-4 Service by mail sufficient notice
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. The Board has no way of knowing whether or not a notice reaches its destination and, therefore, when a notice has been mailed to the person concerned, the duty of the Board has been performed. (Indiana Board of Pharmacy; Reg 2,Sec 4; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 119; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-2-5 Duplicate certificate or drugstore permit; fees (Repealed)

Sec. 5. (Repealed by Indiana Board of Pharmacy; filed Aug 12, 1987, 9:45 am: 11 IR 94)

Rule 3. Experience (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 3.1. Examination and Experience Requirements

856 IAC 1-3.1-1 Licensure by examination
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. All pharmacist applicants for licensure by examination qualified by law and as provided in rules of the board shall take the complete examination consisting of North American Pharmacist Licensure Examination (NAPLEXÔ) and the Multistate Pharmacy Jurisprudence Examination (MPJEÔ). All exams shall be given in the English language only. (Indiana Board of Pharmacy; 856 IAC 1-3.1-1; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-3.1-2 Information for licensure
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. (a) Persons seeking licensure by examination shall file an application on a form supplied by the board.

(b) Persons seeking licensure by examination shall provide the following information on, or submit such information with, the application for licensure:

(1) Complete name, address, and telephone number.

(2) Date and place of birth.

(3) Certification of complete history and structure of hours of pharmacy experience prior to and after graduation.

(4) Intern/extern certificate number, including date and state from which certificate was issued.

(5) Two (2) recent passport-type (2^{2}ˊ 2^{2}) photographs of the applicant, taken within eight (8) weeks prior to filing the application.

(6) The fee as required by 856 IAC 1-27-1.

(7) Either:

certification of graduation from a program approved by the board pursuant to 856 IAC 1-5-1; or

(B) in the case of an applicant applying in the last half-year of the curriculum, certification from the dean of an approved pharmacy program that the applicant is expected to successfully complete the curriculum;

however, the applicant shall not be allowed to sit for the examination until the board has received certification of graduation.

(Indiana Board of Pharmacy; 856 IAC 1-3.1-2; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; filed Aug 12, 1987, 9:45 a.m.: 11 IR 94; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-3.1-3 Passing scores
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. To successfully pass an examination, the applicant must attain a general average of not less than seventy-five (75) on the examination taken after the effective date of this rule. (Indiana Board of Pharmacy; 856 IAC 1-3.1-3; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)

856 IAC 1-3.1-4 Reexamination
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. If an applicant fails an examination or any portion of an examination and wishes to retake the failed portions, the applicant shall file a new complete application, except that the applicant may include affidavits or data concerning his or her experience in a pharmacy and attendance at a college or school of pharmacy by referring to the original application. An applicant who fails to pass a portion of the examination after two (2) sittings shall be permitted to take subsequent examinations, providing the candidate first both appears before the board for consultation, and receives the express written permission of the board. (Indiana Board of Pharmacy; 856 IAC 1-3.1-4; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)

856 IAC 1-3.1-5 Pharmacist intern/extern; experience requirement
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. The period of practical experience required by law for an applicant for a pharmacist license shall be computed and credited from the date of registration as a pharmacist intern/extern, with no credit given for any experience in pharmacy prior to registration or during a period when the registration has lapsed or is suspended or revoked by the board. (Indiana Board of Pharmacy; 856 IAC 1-3.1-5; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-3.1-6 Board approval required for practical experience programs for pharmacist intern/extern registration; pharmacy permit required, exceptions; prior approval of nonpharmacy experience site; minimum-maximum hours of practical experience
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. (a) The Indiana board of pharmacy (board) shall approve all practical experience programs wherever served. Persons responsible for the integrity and content of practical experience programs shall furnish information regarding material changes to the board, prior to implementation, for approval of the program. Approval may be withheld for cause, which may include, but is not limited to, unapproved material change in the program or change in program administration.

(b) All persons wishing to satisfy their practical experience requirements in Indiana shall possess a valid registration as a pharmacist intern or extern in Indiana while the practical experience hours are being served.

(c) If the experience is in a pharmacy that is required by law to have a pharmacy permit, that pharmacy must have a valid pharmacy permit. A pharmacy permit is not required if:

(1) the practical experience is being obtained at a site other than a pharmacy, for example, sites primarily engaged in:

(A) manufacturing;
(B) research;
(C) consulting;
(D) drug information;
(E) drug utilization review; or
(F) other pharmacy-related activity; or

(2) the experience is in a pharmacy that is not required to have a permit, for example, federally owned facilities.

(d) Prior approval is required for experience in a site other than a pharmacy. A written request must be submitted to the board prior to beginning the experience period if:

(1) an individual intern or preceptor is seeking board approval, the request for approval shall include:

(A) a detailed description of the proposed practical experience program with respect to time, place, duties, responsibilities, and supervision; and

(B) the name of the person responsible for supervising the experience; or

(2) an approved college or school of pharmacy is seeking board approval for experiential courses, the request for approval shall include:

(A) a detailed description of the proposed practical experience course with respect to duties, responsibilities, and supervision; and

(B) the name of the course coordinator responsible for site selection and maintenance of the integrity of the program.

(e) Acceptable practical experience time per week shall consist of not less than four (4) and not more than sixty (60) hours of time per week served under the supervision of a pharmacist or another board approved practical experience supervisor. (Indiana Board of Pharmacy; 856 IAC 1-3.1-6; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)

856 IAC 1-3.1-7 Pharmacist intern/extern; program requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 7. (a) Practical experience requirements for pharmacist interns/externs in Indiana may be satisfied by complying with either of the following:

(1) Completion of the practical experience requirements of the college or school of pharmacy from which the intern/extern has graduated, if the curriculum of the college or school has been accredited by:

(A) the American Council on Pharmaceutical Education (ACPE);

(B) the Canadian Council on Pharmacy Accreditation (CCPA); or

(C) another board-approved practical experience program.

(2) In the event the intern/extern has graduated from a nonaccredited program as outlined in subdivision (1) or has no practical experience as a part of that individual's educational curriculum, the

intern/extern must complete a minimum of one thousand five hundred (1,500) hours of practical experience under the supervision of a pharmacist and provide the board, prior to or concurrent with application for licensure, a written description of the objectives and duties of that experience.

(b) If a candidate for licensure as a pharmacist in Indiana has been licensed as a pharmacist in another state or jurisdiction and has been engaged in the practice of pharmacy as defined in IC 25-26-13-2 for a period of not less than one (1) year, the practical experience requirement is waived. (Indiana Board of Pharmacy; 856 IAC 1-3.1-7; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Jan 3, 2000, 10:03 a.m.: 23 IR 1107; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1332)

856 IAC 1-3.1-8 Pharmacist intern/extern; minimum/maximum hours of supervision (Repealed)

Sec. 8. (Repealed by Indiana Board of Pharmacy; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878)

856 IAC 1-3.1-9 Pharmacist intern/extern; practical experience affidavits

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 9. The acceptable pharmacist intern or pharmacist extern practical experience time must be verified by practical experience affidavits signed at the termination of each period of practical experience. All such affidavits must list all practical experience time on a calendar week basis showing actual time served each week. (Indiana Board of Pharmacy; 856 IAC 1-3.1-9; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2877; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-3.1-10 Pharmacist intern/extern; unacceptable experience time (Repealed)

Sec. 10. (Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)

856 IAC 1-3.1-11 Out-of-state externship and other practical experience programs; postgraduate requirements; taking the licensure examination before completion of practical experience

Authority: IC 25-26-13-4
Affected: IC 25-26-13-11

Sec. 11. (a) Time accepted for experience gained in approved school supervised practical experience programs in other states successfully completed while enrolled in a professional degree program recognized under IC 25-26-13-11(a)(3) will be credited toward fulfillment of experience hours required under section 7 of this rule. Time accepted for practical experience obtained while not enrolled in a professional degree program and approved under section 6 of this rule may be credited to experience requirements at the board's discretion, whether or not served in Indiana.

(b) A description of the out-of-state practical experience program with the number of hours it contains shall be submitted with the certification for evaluation by the board subject to the following:

(l) Students supplying detailed information on their program at least eight (8) weeks in advance of the board examination date will have their hours evaluated to determine the number that will be accepted toward the prelicensure five hundred twenty (520) hour requirement.

(2) Students not supplying sufficient detailed information on their program or failing to submit the same within eight (8) weeks before the board examination to allow evaluation may take the exam prior to the evaluation of their program. After evaluation, they will be notified of the hours that may be accepted. If sufficient hours are not accepted, licensure will not be granted.

(c) A candidate for licensure who has graduated from an approved school of pharmacy may take the examination before completing the required practical experience hours. However, the candidate will not be licensed as a pharmacist until affidavits are received for the entire practical experience requirement. (Indiana Board of Pharmacy; 856 IAC 1-3.1-11; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; errata, 9 IR 1101; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2877; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-3.1-12 Out-of-state practical experience; reciprocity

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 12. Practical experience time served in another state will be accepted and will permit the applicant to take the NAPLEX examination subject to section 11 of this rule if the following requirements are met:

(1) The practical experience time served in such other state meets all requirements of Indiana law and is experience time of the type that is acceptable to the Indiana board of pharmacy (board).

(2) The applicant has a valid intern or apprentice license from the state where the experience is served. Or, if that other state does not require an intern or apprentice license, the applicant must submit certification or an affidavit from the secretary of the board that state showing that no intern or apprentice license is required.

(Indiana Board of Pharmacy; 856 IAC 1-3.1-12; filed Dec 3, 1985, 3:02 p.m.: 9 IR 769; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1332)

856 IAC 1-3.1-13 Fraud or misrepresentation in applying for or taking examination

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 13. Any misrepresentation made or any fraud perpetrated in an application for examination, or in the examination, shall be deemed sufficient cause for the refusal of such application, or to complete such examination, and if such misrepresentation or fraud is not discovered until later than at the time of the submission of such application, or until the completion of such examination, it shall be deemed sufficient cause for the dismissal from the examination, or the refusal to grant a certificate, or the revocation of the certificate if already issued, and the fee paid with such application for such examination shall be forfeited; provided, however, that the action of the board shall be subject to the law in force with respect to the denial of a license or permit on application. (Indiana Board of Pharmacy; 856 IAC 1-3.1-13; filed Dec 3, 1985, 3:02 pm: 9 IR 769; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 4. Reciprocity and License Transfer

856 IAC 1-4-1 License transfer

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. All applicants for license transfer registration must submit their application, with a certified photograph of the applicant and if necessary a copy of their birth certificate attached thereto, and may be requested to appear in person before the Indiana board of pharmacy (board) for a personal interview during a board meeting. An Indiana law examination must be passed before any certificate of licensure will be issued. A practical examination will be administered to the applicant if the board determines that the applicant has not been actively practicing pharmacy in the twelve (12) months preceding the application.

Applications for license transfer must be reviewed and approved at a board meeting prior to examination and prior to the applicant's board requested personal appearance. (Indiana Board of Pharmacy; Reg 4, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; filed Dec 3, 1985, 3:02 p.m.: 9 IR 769; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

856 IAC 1-4-2 Application forms
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. All applicants applying for license transfer in Indiana are required to make application on the official application blanks issued by the National Association of Boards of Pharmacy. (Indiana Board of Pharmacy; Reg 4,Sec 2; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

856 IAC 1-4-3 Restoration of Indiana certification by reciprocity (Repealed)

Sec. 3. (Repealed by Indiana Board of Pharmacy; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878)

856 IAC 1-4-4 Qualifications of applicants for license transfer
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. Applicants for license transfer will be admitted to Indiana only if their qualifications for licensure, possessed at the time of their original registration in the state from which they came, were equal to the requirements of Indiana at that time. (Indiana Board of Pharmacy; Reg 4,Sec 4; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 120; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

Rule 5. Recognition of Accredited Schools

856 IAC 1-5-1 Recognition of accredited schools or colleges (Repealed)

Sec. 1. (Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)

Rule 6. Drugstores, Pharmacies, Apothecary Shops (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Jun 20, 2001, 3:59 p.m.: 24 IR 3651)

Rule 6.1. Drugstores, Pharmacies, Apothecary Shops

856 IAC 1-6.1-1 Pharmacy equipment; lack of access between adjacent pharmacies
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 1. (a) In addition to the requirements of IC 25-26-13-18, the qualifying pharmacist for each pharmacy issued a permit by the board shall be responsible for all decisions concerning the additional fixtures, facilities, and equipment needed by the pharmacy to operate properly in compliance with the law regulating pharmacies. In making those decisions, the qualifying pharmacist shall consider minimum health, safety, and security measures as well as the type and scope of practice, the patient's needs, and the laws and rules that apply.

(b) If requested by a representative of the Indiana board of pharmacy (board), the qualifying pharmacist shall justify, in writing, all decisions made under this rule.

(c) The board shall determine whether minimum health, safety, and security measures have been satisfactorily met by an applicant for a pharmacy permit before the permit is issued or at any time the permit is in effect.

(d) If the board determines that a pharmacy does not meet the requirements of IC 25-26-13-18 and this rule, it will identify and notify the qualifying pharmacist of the deficiencies. The qualifying pharmacist shall correct or cause to be corrected the deficiencies identified within thirty (30) days of notification by the board of the noncompliance.

(e) Failure to timely correct the deficiencies identified is grounds for denial or revocation of a permit.

(f) To assure that no pharmacy is left unattended by a pharmacist while that pharmacy is in operation, no means of access may be constructed or maintained between adjacent pharmacies. (Indiana Board of Pharmacy; 856 IAC 1-6.1-1; filed Jun 20, 2001, 3:59 p.m.: 24 IR 3651)

Rule 7. Pharmacy Permits

856 IAC 1-7-1 Change of pharmacy ownership
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 1. In case of change of ownership of a pharmacy the original permit becomes void and must be returned, by the new owner, with application to the Board of Pharmacy for a new permit. (Indiana Board of Pharmacy; Reg 7,Sec 1; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-7-2 Application for permit to conduct pharmacy
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. All applications for a permit to conduct a pharmacy will require the action of at least a quorum of the Board. (Indiana Board of Pharmacy; Reg 7,Sec 2; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-7-3 Relocation of pharmacy
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11; IC 25-26-13-18

Sec. 3. To be eligible for relocation of a pharmacy an applicant must show to the satisfaction of the board that the requirements for the eligibility for a pharmacy permit as set out in IC 25-26-13-18 will be met. Prior to relocating a pharmacy the proprietor shall file an application, on a form prescribed and furnished by the board, setting out all information so requested on such form. Prior to moving a pharmacy, after receipt of board approval, the permit holder shall submit the premises to a qualifying inspection by a representative of the board. (Indiana Board of Pharmacy; Reg 7, Sec 3; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; filed Dec 3, 1985, 3:02 pm: 9 IR 770; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-7-4 Licensed pharmacist required for each pharmacy
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. Every application for a permit to operate a pharmacy must set forth the name of the pharmacist, licensed by the Indiana board of pharmacy, who will be in full responsible charge for the legal operation of the pharmacy under said permit. Any person, firm, corporation, co-partnership or association owning or operating more than one pharmacy must secure a permit for each such pharmacy and no single registered pharmacist shall be permitted to qualify for more than one store. Provided, however, nothing in this regulation shall be construed to apply to the ownership of such pharmacy but shall apply only to the issuance of permits for the operation of such pharmacy. (Indiana Board of Pharmacy; Reg 7, Sec 4; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 122; filed Dec 3, 1985, 3:02 pm: 9 IR 770; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-7-5 Pharmaceutical consultation service for extended care facilities; notice to board

Authority: IC 25-26-13-4

Affected: IC 25-26-13-4

Sec. 5. For extended care facilities, nursing homes, clinics, rest homes, homes for the aged, governmental agencies and other places where a pharmacy permit is not held nor drugs stored with the exception of an emergency kit, the pharmacist providing pharmaceutical consultation service shall notify initially and annually in each instance such practice and place with the Indiana Board of Pharmacy on forms provided by the Board. If consulting pharmacist services are terminated by an individual, he shall notify the Board and the newly appointed consulting pharmacist shall then register with the Indiana Board of Pharmacy. (Indiana Board of Pharmacy; Reg 7,Sec 5; filed Jul 21, 1972: Rules and Regs. 1973, p. 532)

856 IAC 1-7-6 Consulting pharmacist and dispensing pharmacist; definitions

Authority: IC 25-26-13-4

Affected: IC 25-26-13-2

Sec. 6. A consulting pharmacist shall be defined as a pharmacist holding a valid pharmacist's license in the State of Indiana, who has been designated by the facility served as consulting pharmacist and who has duly been recorded as same by the Indiana Board of Pharmacy.

The dispensing pharmacist(s) shall be defined as those registered pharmacists holding valid pharmacist's license in the State of Indiana who are supplying drugs and pharmaceuticals to the facility from a licensed pharmacy facility in the State of Indiana. (Indiana Board of Pharmacy; Reg 7,Sec 6A; filed Jul 21, 1972: Rules and Regs. 1973, p. 532)

856 IAC 1-7-7 Duties of consulting pharmacist

Authority: IC 25-26-13-4

Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 7. A consulting pharmacist's duties should include the following:

(1) To insure compliance with state and federal laws, regulations and codes.

(2) To ascertain that there are adequate drug and pharmacological references for the physician, pharmacy, and nursing personnel, and to maintain an adequate professional pharmaceutical library.

(3) Be responsible to initiate and maintain in each instance when applicable, appropriate records and procedure for the receipt, labeling, storage and disposition of all drugs, including investigational drugs, medication samples, and emergency kits.

(4) The consulting pharmacist, even though employed by the nursing home shall respect the patient's freedom of choice of pharmaceutical service.

(5) Make periodic inspection of all medication (individual prescriptions), remove unused medications, and containers from which medication has been discontinued. All medication shall be destroyed when the physician orders that its use shall be discontinued or when the patient has been discharged or is deceased. The Consulting Pharmacist shall insure the fact that a physician has written a separate order if he wishes the medication to be sent home or transferred with the patient.

(6) Participate in the Professional Policy Committee of the facility.

(7) Provide educational in-service training on pharmaceuticals and therapeutics to the staff members of the facilities.

(8) At the time of State Board of Health Inspections of the facility, the consulting pharmacist shall be present for the medication and drug storage inspection.

(9) Maintain adequate control measures for all emergency drugs if the facility finds it necessary to utilize an emergency kit. (Emergency drugs for facilities as expressed above are defined as those drugs, the prompt use and immediate availability of which are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen adverse changes in the patient's condition which threaten the patient's life or well being.) The consulting pharmacist shall check and shall maintain adequate records in restocking the emergency kit and recording distribution. The dispensing pharmacist shall provide a list of the contents of the kit to be placed on the outside so that it is readily available for the physician to know its contents. The dispensing pharmacist shall insure that the physician ordering emergency medication shall authorize a prescription order for the replenishment and after replenishment the dispensing pharmacist shall seal the kit by lock or some suitable means. The seal or lock shall only be broken or opened pursuant to a physician's emergency order by a person legally authorized to administer such drugs or by the dispensing pharmacist. The dispensing pharmacist shall indicate on the emergency kit an expiration date which in no case shall be later than twelve months from the date of issue of the sealed or locked kit. Once the emergency kit is used and its seal broken or lock opened (or after twelve months in the case of an unused kit), the kit shall be returned promptly to the dispensing pharmacist for restocking and resealing. The strength, quantity and expiration date shall appear for the contents on the external list. A copy of this list shall be given the administrator and the consulting pharmacist and the original retained by the dispensing pharmacist.

(Indiana Board of Pharmacy; Reg 7,Sec 6B; filed Jul 21, 1972: Rules and Regs. 1973, p. 532)

Rule 8. Known Pharmaceutical Manufacturer and Manufacturer Definition

856 IAC 1-8-1 Known pharmaceutical manufacturer; definition (Repealed)

856 IAC 1-8-2 “Manufacturer” defined (Repealed)

Rule 9. Application for Prohibited Drugs (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 10. Non-Drug Products (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 11. Toxic Preparations (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 12. Poisons (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)

Rule 13. General Definitions

856 IAC 1-13-1 Calendar week (Repealed)

Sec. 1. (Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

856 IAC 1-13-2 "Be in personal attendance" defined (Repealed)

Sec. 2. (Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

856 IAC 1-13-3 "Prescription department closed" closing hours; electronic monitoring; applicability

Authority: IC 25-26-13-4

Affected: IC 25-26-13-10; IC 25-26-13-19

Sec. 3. (a) This section and section 4 of this rule implement IC 25-26-13-19 concerning board approval for Type I and Type VI pharmacies to be opened to the general public without a pharmacist on duty. This section and section 4 of this rule apply only in situations where the entire area of the business is licensed as a pharmacy. This section, section 4 of this rule, and IC 25-26-13-19 do not apply where the only area of a business licensed as a pharmacy is the prescription department.

(b) The following definitions apply throughout this section:

(1) "Absence of pharmacist" means those periods when the prescription department is closed and secured and the pharmacist is not present in the pharmacy.

(2) "Electronic monitoring system" means a system having the ability by light beam, heat, motion, or other electronically activated method to detect the presence of unauthorized persons or instrumentalities in a given area, and relay or report that detection as described in this section.

(3) "Prescription department" means that area of the pharmacy where the legend drugs, devices, and other merchandise or items which can only be dispensed or delivered by a pharmacist are located and which must be secured in the absence of the pharmacist.

(4) "Reasonable barrier" means an obstruction or barricade that blocks or impedes the entry into the area by an ordinary person, and includes, but is not limited to, a latched or locked gate of sufficient height and construction that an ordinary person cannot breach the barrier and/or violate the space being monitored without detection.

(5) "Secured" means either of the following:

(A) An area is completely enclosed as to its perimeter, from floor to ceiling, and locked.

(B) Through installation of reasonable barriers, an area not readily accessible which is monitored by a board approved electronic monitoring system covering all portions of the secured areas.

(c) Before a pharmacy may be open to the general public without a pharmacist on duty, the pharmacy must file an application with the board and have it approved by the board under IC 25-26-13-19. The pharmacy must abide by the closing hours designated in the application. Any change from the hours as stated in the application must be submitted in writing to the board.

(d) Under IC 25-26-13-19, a prescription department may be locked or secured while the remainder of the pharmacy remains open to the public if the following criteria are met:

(1) The prescription department is constructed in such a manner or located in such an area that reasonable barriers are in place which prevent the easy and/or quick access to legend drugs and other articles which are in the prescription department. These barriers may be doors or other obstacles as the occasion requires.

(2) The prescription department, if not secured and locked as described in subsection (b)(5)(A), must be secured and monitored by a board approved electronic monitoring device that provides the following:

(A) On-site audible alarm that is clearly and continuously audible at all points within the pharmacy.

(B) Off-site audible or visual alarm that is continuously monitored at all times that the pharmacy remains open while the prescription department is closed and secured.

(3) Any violation or breach of the secured area shall be duly recorded by the qualifying pharmacist of the pharmacy and by the off-site security monitoring agency and reported to the board within seventy-two (72) hours of the violation or breach. This report shall include the nature of the violation or breach.

(4) Facilities monitored electronically must provide for backup power for the eventuality that there is an electronic power failure for any reason. Such backup power shall be capable of continuing the monitoring for a period of no less than thirty-six (36) hours.

(5) The electronic monitoring system shall be activated and inactivated only by key or combination. Alarms which have been triggered shall only be reset and/or reactivated by a pharmacist. The key or combination shall only be in the possession or knowledge of a pharmacist. Reasonable exceptions shall be made to this for security system operators. However, in no case shall a security system operator have access to the secured area without the presence of a pharmacist. Such exceptions shall be listed in the application under this section and shall be subject to approval by the board.

(e) Under IC 25-26-13-10(b), the board may revoke or limit the privilege to be open to the general public without a pharmacist on duty if the pharmacy violates this section or section 4 of this rule. (Indiana Board of Pharmacy; Reg 13, Sec 3; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 124; filed May 15, 1992, 5:00 p.m.: 15 IR 2246; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-13-4 Record of hours open without a pharmacist on duty

Authority: IC 25-26-13-4; IC 25-26-13-19

Affected: IC 25-26-13-4; IC 25-26-13-19

Sec. 4. The pharmacist shall maintain a record stating any hours that the pharmacy has been open for business without having a pharmacist on duty if those hours vary from the hours listed in the application under section 3(c) of this rule. Entries in this written record shall be made in ink of the time the pharmacist is absent. The written record shall be maintained in the pharmacy and shall be available for examination by members of the board or their inspectors for a period of not less than two (2) years from the date of the last entry in the record. (Indiana Board of Pharmacy; Reg 13, Sec 4; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 125; filed May 15, 1992, 5:00 p.m.: 15 IR 2247; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-13-5 Legend drugs (Repealed)

Sec. 5. (Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 14. Physical Inventory of Merchandise (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 15. Pharmacists' Notification of Termination

856 IAC 1-15-1 Pharmacist leaving employ of pharmacy; notice to board; application to qualify permit

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-18

Sec. 1. If a qualified pharmacist, who, having upon the basis of his or her qualifications caused a pharmacy permit to be granted to any person, firm, corporation or copartnership desiring to operate, maintain, open or establish a pharmacy should leave the employ of such pharmacy, he or she shall immediately notify the Indiana board of pharmacy (board) and the owner shall file an application with the board to qualify the permit with another pharmacist. (Indiana Board of Pharmacy; Reg 15, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 125; filed Dec 3, 1985, 3:02 p.m.: 9 IR 771; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

Rule 16. New Pharmacist (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 17. Practice of Pharmacy (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 18. Narcotic License (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 19. Adoption by Reference of U.S. Federal Rules Pertaining to Narcotics (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 20. Violations and Penalties

856 IAC 1-20-1 Prohibitions
Authority: IC 25-26-13-4
Affected: IC 16-1-30; IC 16-6-8; IC 25-26; IC 35-48

Sec. 1. A pharmacist licensed to practice pharmacy under IC 25-26-13-1 through 25-26-13-29, or a pharmacist extern or a pharmacist intern licensed under IC 25-26-13-10, as a part of the responsibility, to not knowingly violate the Indiana board of pharmacy's (board's) standards for the competent practice of pharmacy shall not do the following:

(1) Violate the Uniform Indiana Controlled Substances Act found at IC 35-48-1-1 through 35-48-4-14, as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the Uniform Indiana Controlled Substances Act, which were effective by January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(2) Violate the Indiana Legend Drug Act found at IC 16-6-8-1 through 16-6-8-9, as amended up to and including January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(3) Violate IC 16-1-30-1 through IC 16-1-30-19, as amended to and including January 1, 1983, which deal with adulterated and misbranded drugs or devices, or any rules promulgated by the board under the authority of IC 16-1-30-1 through IC 16-1-30-19, which were effective as of January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(4) Violate 21 U.S.C. 801 through 21 U.S.C. 1191, as amended, up to January 1, 1983, which deal with drug abuse and any of the rules and regulations promulgated under the authority of said Title and Sections as of January 1, 1983, insofar as such violations would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(5) Violate the Federal Food, Drug, and Cosmetic Act, which is found at 21 U.S.C. 301 through 21 U.S.C. 392, as amended, up to January 1, 1983, or any rules or regulations promulgated under the authority of the said act as of January 1, 1983, insofar as such violation would pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.

(6) Violate Executive Proclamations of the President of the United States, which were effective by January 1, 1983, which pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.

(7) Sell, as defined in IC 25-26-13-2, controlled substances or legend drugs with or without prescription, where such sale or distribution is not in good faith and enables the person to whom the sale is made to supply or divert the controlled substances or legend drugs in an unlawful manner. The sale or distribution of controlled substances or legend drugs in unusually large amounts and within an unusually short period of time to the same individual is considered to be against the public welfare, health and safety and may be determined to be a sale or distribution not in good faith.

(8) Sell, as defined in IC 25-26-13-2, to the public any drugs, biologicals, medicinal substances, or devices when such pharmacist knows such drugs, biologicals, medicinal substances, or devices to be forgeries or a counterfeit product or beyond the manufacturer's expiration date.

(9) Aid or abet in the practice of a pharmacy a person not having a license to practice as a pharmacist in Indiana.

(10) Practice pharmacy in such a manner as to amount to incompetency or negligence in the sale or dispensation of legend drugs as defined in the Indiana Legend Drug Act under IC 16-6-8-2 or controlled substance as defined in the Uniform Controlled Substances Act of 1973, under IC 35-48-1-1.

(11) Violate the act regulating the practice of pharmacy in Indiana, which is codified at IC 25-26-13-1 through IC 25-26-13-29 as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the said act, which were effective by January 1, 1983.

(Indiana Board of Pharmacy; Reg 20; filed Nov 17, 1978, 2:06 p.m.: 2 IR 63; filed Jul 28, 1983, 9:01 a.m.: 6 IR 1745; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

Rule 21. Resale of Returned Substances

856 IAC 1-21-1 Resale of returned substances
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) This section implements and interprets IC 25-26-13-25(h) concerning the resale or redistribution of medications.

(b) For a medication to have been properly stored and securely maintained according to sound pharmacy practices, the storage and administration of medications in the institutional facility must be under the immediate control of licensed nursing personnel.

(c) If the medication was originally packaged by the dispensing pharmacy, it cannot be resold or redistributed unless:

(1) the medication has been repackaged into unit-dose packaging using packaging materials that meets Class A or Class B standards, found in the United States Pharmacopeia (U.S.P.), page 1574, published by the United States Pharmacopeia, 22nd Revision, January 1, 1990, United States Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, which standards are incorporated herein by reference; and

(2) the repackaging process complies with the standards as found in the "Proper Treatment of Products Subjected to Additional Manipulations, Section 1191" of the United States Pharmacopeia, page 1705, 22nd Revision, 1990, which section is incorporated herein by reference.

(d) A medication repackaged under the provisions of subsection (c) shall be labeled with an expiration date of not greater

than one (1) year until the manufacturer's expiration date, whichever is earlier. (Indiana Board of Pharmacy; Reg 21, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 128; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1334)

Rule 22. Narcotics Defined (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 23. Dispensing of Dangerous Drugs

856 IAC 1-23-1 Dispensing of dangerous drugs

Authority: IC 25-26-13-4

Affected: IC 16-42-22; IC 25-26-13-4; IC 25-26-13-11

Sec. 1. In the sale or dispensing of any prescription drug or narcotic, the pharmacist shall be required to affix to the immediate container in which such prescription drug or narcotic is delivered a label bearing the following information:

(1) The name, address, and telephone number of the establishment from which such drug was sold.

(2) The date on which the prescription for such drug was filled.

(3) The number of such prescription as filed in the prescription files of the pharmacy where the prescription was filled.

(4) The name of the practitioner who prescribed such drug.

(5) The name of the patient, and if such drug was prescribed for an animal, a statement of the species of the animal and the owner's name.

(6) The directions for use of the drug as contained in the prescription.

(7) The name of the drug (trade or generic, or both) in compliance with the Generic Drug Law found in IC 16-42-22.

(Indiana Board of Pharmacy; Reg 23,Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 129; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335)

Rule 24. Hospital Pharmacies (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Jun 8, 1982, 10:04 am: 5 IR 1420)

Rule 25. Internship for Apprentice Pharmacists (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 26. Continuing Professional Education

856 IAC 1-26-1 Continuing professional education; general requirements; definitions

Authority: IC 25-26-13-4

Affected: IC 25-1-9-3; IC 25-26-13-14

Sec. 1. (a) The following definitions apply throughout this rule:

(1) "Continuing professional education" or "continuing education" means accredited postlicensure professional educational experience derived from participation in postgraduate studies, institutes, seminars, lectures, conferences, workshops, and such other forms of educational experiences so as to maintain the professional competency of the practice of pharmacy, improve pharmacy professional skills, and preserve pharmaceutical standards for the purpose of the protection of the health and welfare of the citizens of Indiana.

(2) "Hours" means measurement of value applied to a particular accredited continuing pharmacy educational activity as assigned by the Indiana board of pharmacy (board) relative to maintaining the competency of a pharmacist.

(3) "Contact hour" means not less than fifty (50) nor more than sixty (60) minutes of clock time participating in a continuing education program.

(4) "Continuing education unit" or "CEU" means ten (10) contact hours of continuing education credit.

(5) "Approved by ACPE" means pharmacy continuing education providers that meet the requirements of "The ACPE Continuing Education Provider Approval Program Criteria for Quality and Interpretive Guidelines" as published by the American Council on Pharmaceutical Education, Inc., Chicago, Illinois on July 1991.

(b) In order to qualify for licensure renewal, a pharmacist must meet the continuing professional education requirements as follows:

(1) Thirty (30) hours (three (3) CEUs) of continuing education as required by this rule shall be required each biennium.

(2) No hours may be carried forward from one (1) biennium to another. However, if a pharmacist fails to meet the requirements of this rule during the biennial period, the pharmacist may earn and report sufficient hours during a succeeding biennium and apply the continuing education hours retroactively to the previous biennium as if they had been earned in that previous biennium in order to qualify for renewal of the pharmacist's license. In the event a pharmacist applies credits to a previous biennium for the reasons stated in this section, those credits may not be used for any other biennium.

(3) All continuing education program hours from sponsors not approved by ACPE must be evaluated and accepted by the board.

(4) Continuing education biennium shall be that time period consisting of January 1 of all even-numbered years through December 31 of the following odd-numbered year.

(c) Accredited continuing education hours may be compiled in the following ways if the sponsor grants the participant a certificate of completion:

(1) Cassette and audio-visual presentation.

(2) In-company professional seminars.

(3) Accredited school of pharmacy continuing education programs.

(4) Postgraduate courses in pharmaceutical sciences.

(5) Correspondence courses.

(6) Programs granted continuing education credit by other states.

(7) Continuing education television series.

(8) Programs sponsored by professional groups in public health provider services.

(9) Professional society and association sponsored program.

(10) Approved business, management, and computer courses.

(11) Programs of sponsors approved by ACPE.

(d) Accredited continuing education hours may be compiled from other programs and experiences if they are evaluated and accepted by the board as meeting the definition of continuing professional education as found in subsection (a)(1).

(e) As provided in subsection (b)(3), continuing education sponsors (hereinafter referred to as sponsors) are responsible for submitting continuing education programs to the board for approval in addition to the following:

(1) A sponsor shall be any person, school, association, or corporation who develops a continuing education program.

(2) The continuing education program must receive approval of the board for final acceptance.

(3) If a sponsor wishes to notify prospective participants in advance of the value (in hours or in CEUs) of a program, the content of the program shall be submitted to the board for evaluation. If the sponsor does not submit the content for evaluation, the sponsor shall note in all material relevant to the program that it has not been evaluated and the hours of credit listed are subject to review by the board.

(4) Sponsors shall receive written notice from the board for approval or disapproval from the board. Approved programs shall be given an identification number stating the year and hourly value.

(5) Program changes must be made to and accepted by the board or the evaluation and acceptance of the program becomes null and void.

(6) Continuing education credit may be granted only once for each program to any individual participant.

(7) Any member of the board shall have the right to attend and participate in any continuing education program.

(8) Programs may be evaluated after presentation or participation if a written request is made to the board within ninety (90) days of the date of presentation.

(9) Sponsors shall retain a file of participants' program completion for four (4) years.

(10) When applying to the board for credit, sponsors shall supply the following information on the application for continuing education course approval, supplied by the board:

(A) Name and address of applicant.

(B) Program title.

(C) Location, date, and time of program.

(D) Sponsoring organization.

(E) Type of program.

(F) Name and qualification of each speaker.

(G) Three (3) learning objectives for the program.

(H) Contact hours of the course.

(I) Method for evaluating the program.

(f) Pharmacists licensed with the board (hereinafter called participants) have the following responsibilities:

(1) Obtain a minimum of thirty (30) hours of continuing education per biennium unless first licensed during the biennium which would make those newly licensed individuals subject to subdivision (5):

(A) a maximum of one-fifth ($^1/_5$) of the total hours may be business, management, or computer courses;

(B) at least four-fifths ($^4/_5$) of the total hours must be pharmacy practice related; and

(C) at least one-half (½) of the total hours must be provided by sponsors approved by ACPE.

(2) Report program name, identification number, and approved hours of continuing education to the board at the time of license renewal.

(3) Retain a file of certificates of completion for four (4) years from the end of the biennium for which the continuing education applied in order to provide copies of certificates upon request for the board's periodic audit of continuing education compliance.

(4) Earn one and one-fourth (1.25) hours of continuing education credit for each month or part of a month from date of licensure until the end of the biennium in which licensure originates if the pharmacist becomes licensed during the biennium. However, a pharmacist who becomes newly licensed for the first time in any state in the last six (6) months of the biennium shall not be required to complete any continuing education for the biennium.

(5) Continuing education hours may be transferred from another state to Indiana if the transfer state recognizes Indiana continuing education hours.

(g) Failure to comply with any one (1) or all of the provisions of this rule while continuing to hold a license as a pharmacist in Indiana shall constitute professional incompetence by failing to keep abreast of current professional theory or practice under IC 25-1-9-3(a)(4)(B) and the pharmacist is subject to discipline under IC 25-1-9. (Indiana Board of Pharmacy; Reg 29; filed Mar 1, 1974, 3:05 p.m.: Rules and Regs. 1975, p. 516; filed Oct 26, 1984, 3:26 p.m.: 8 IR 212; filed Jan 21, 1994, 3:00 p.m.: 17 IR 1096, eff Jan 1, 1994 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #93-152 was filed Jan 21, 1994.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335)

Rule 27. Fee Structure

856 IAC 1-27-1 Fees
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) The fee for licensure by examination as a pharmacist shall be an administrative fee of one hundred dollars ($100).

(b) The fee for licensure as a pharmacist from another state by reciprocity (also known as "license transfer") and without a full examination shall be one hundred dollars ($100.)

(c) The fee for taking or retaking the state jurisprudence examination or the practical examination shall be twenty-five dollars ($25).

(d) The fee for the renewal of a license as a registered pharmacist shall be seventy-five dollars ($75) per year. The board shall collect an additional five dollars ($5) per year from each individual who renews a pharmacist license to fund a program to assist impaired pharmacists.

(e) The fee for a license as a pharmacist intern/extern shall be ten dollars ($10). The renewal fee for such a license shall be ten dollars ($10).

(f) The fee for both an initial application and renewal to operate an in-state pharmacy shall be one hundred dollars ($100) per year. When there is a change of ownership, a new permit must be obtained, and the fee shall be fifty dollars ($50). When there is a change of location, the current permit is updated and the fee is fifty dollars ($50).

(g) The fee for certificate of qualifications, registration, and grades in any application for reciprocity to another state shall be ten dollars ($10).

(h) There will be no fee for a duplicate pharmacy license or duplicate pharmacist pocket license.

(i) The fee for a duplicate pharmacist's wall certificate shall be ten dollars ($10).

(j) The fee for a complete compilation of the pharmacy laws shall be ten dollars ($10).

(k) The fee for both an initial registration and renewal registration of a nonresident pharmacy shall be one hundred dollars ($100) per year.

(Indiana Board of Pharmacy; Reg 29; filed Aug 30, 1977, 8:25 a.m.: Rules and Regs. 1978, p. 660; filed Mar 5, 1985, 2:42 p.m.: 8 IR 802; filed Nov 13, 1985, 3:08 p.m.: 9 IR 772; filed Apr 30, 1986, 9:43 a.m.: 9 IR 2204; filed Sep 8, 1987, 2:30 p.m.: 11 IR 95; filed Jul 24, 1991, 2:45 p.m.: 14 IR 2238; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3106; filed May 29, 1998, 11:56 a.m.: 21 IR 3931; filed Aug 5, 1998, 3:48 p.m.: 21 IR 4535) NOTE: Renumbered Reg 30 by 1978 Amendment. *(Note: Fee language proposed 10/01 and approved by Board; not yet effective as of this document's printing. Approximately effective: 5/02)*

Rule 28. Institutional Pharmacies and Pharmacy Services

856 IAC 1-28.1-1 Definitions
Authority: IC 26-26-13-4
Affected: IC 16-42-19-5; IC 25-6-3-7; IC 25-26-13

Sec. 1. In addition to the definitions in IC 25-26-13-2 and for purposes of this rule, the following definitions apply throughout this rule:

(1) "Cabinet" includes a mechanical storage device for dispensing drugs. The term means a locked or secured enclosure located outside the pharmacy licensed area:

(A) to which only specifically authorized personnel may obtain access by key or combination available only to those authorized persons by:

(i) security code;

(ii) password; or

(iii) other method of positively identifying an individual; and

(B) that is sufficiently secure to deny access to unauthorized persons.

(2) "Cognitive services" means those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information.

(3) "Consultant pharmacist" means a pharmacist licensed pursuant to IC 25-26-13-11 and who engages in the practice of pharmacy in or for long term care facility or other residential patients, other than as a supplying pharmacist.

(4) "Consulting" means the provision of nonsupply related cognitive services that include, but are not necessarily limited to, the following:

(A) Drug regimen review as defined in IC 25-26-13-2.

(B) Provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the health care providers of the facility regarding the appropriateness, use, storage, handling, administration, and disposal of drugs within the facility.

(C) Participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration, and disposing of drugs and devices.

(D) Assuring the compliance with all applicable laws, rules, and regulations.

(E) Provision of educational and drug information sources for the education and training of the facility health care professionals.

(F) Accepting responsibility for the implementation and performance of review of quality-related or sentinel events as defined in this rule.

(5) "Emergency drugs" means those drugs that:

(A) may be required to meet the immediate therapeutic needs of patients; and

(B) are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from other sources.

(6) "Institutional facility" means any health care facility whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where practitioners, as defined by IC 16-42-19-5, who are duly licensed, engage in private practice and pharmacies licensed under IC 25-26-13-17.

(7) "Institutional pharmacy" means that portion of an institutional facility where pharmacy is practiced and is:

(A) the location of the selection, compounding, production, sale, storage, and distribution of drugs, devices, and investigational or new drugs used in the diagnosis and treatment of injury, illness, and disease pursuant to drug orders and prescriptions by practitioners; and

(B) licensed with the board under IC 25-6-3-7.

(8) "Performance improvement program" means a continuous, systematic review of key medication use processes to identify, evaluate, and improve medication use and patient care.

(9) "Pharmacist in charge" (by whatever title, for example, "pharmacy manager","pharmacy director", or "director of pharmacy") means the pharmacist who directs the activities of the institutional pharmacy and who is, as such, responsible for:

(A) all activities of the institutional pharmacy; and

(B) meeting the requirements of:

(i) IC 25-26-13;

(ii) the rules of the board; and

(iii) any federal requirements pertaining to institutional pharmacies.

The qualifying pharmacist may, depending on the circumstances, also be the pharmacist in charge, though the pharmacist in charge is not required to be the qualifying pharmacist.

(10) "Policy and procedure manual" means a written document containing the agreed-to institutional rules of operation and methodology for the effective delivery of pharmacy services.

(11) "Qualifying pharmacist" means the pharmacist who accepts responsibility for the operation of a pharmacy as defined in IC 25-26-13-2 and whose name is listed on the pharmacy permit granted under IC 25-26-13-17.

(12) "Quality-related event" means the inappropriate provision of pharmaceutical services whether or not resulting in an adverse health incident, including the following:

(A) A variation from the practitioner's order, including, but not limited to, the following:

(i) Dispensing an incorrect drug.

(ii) Dispensing an incorrect drug strength.

(iii) Dispensing an incorrect dosage form.

(iv) Dispensing a drug to a wrong patient.

(v) Providing inadequate or incorrect packaging, labeling, or directions.

(vi) Failing to provide an ordered drug.

(B) A failure to identify and manage:

(i) over-utilization or under-utilization;

(ii) therapeutic duplication;

(iii) drug-disease contraindications;

(iv) drug-drug interactions;

(v) incorrect drug dosage or duration of therapy;

(vi) drug-allergy interactions; or

(vii) clinical abuse and/or misuse.

(13) "Reversible condition" means a condition that requires intervention to resolve in a reasonable time.

(14) "Sentinel event" means an unexpected occurrence involving serious adverse effect, such as disability, life threatening condition, prolonged hospitalization, or death in a patient resulting from medication use.

(15) "Supplying pharmacist" means that pharmacist licensed in the state where the pharmacist is practicing and who is practicing in a supplying pharmacy (as defined in this rule) and who accepts responsibility for all aspects the drugs and devices sold (as defined in IC 25-26-13-2) or dispensed to a facility.

(16) "Supplying pharmacy" means a pharmacy licensed in the state where the pharmacy is located, and which provides drugs and devices to patients in long term care or other facilities where patients reside.

(17) "Temporary condition" means a condition that resolves in a reasonable time without intervention.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-1)

856 IAC 1-28.1-2 Purpose
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 2. The purpose of this rule is to set forth the responsibilities of pharmacists and pharmacies serving institutional and home health care patients.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-2)

856 IAC 1-28.1-3 Applicability
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 3. This rule is applicable to pharmacies located:

(1) within institutional facilities as defined in section 1 of this rule and classified as Type II pharmacies in IC 25-26-13-17; and

(2) outside institutional facilities that serve institutionalized patients who are classified as Type III and Type VI pharmacies as in IC 25-26-13-17.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-3)

856 IAC 1-28.1-4 Pharmacist in charge; responsibilities
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 4. The pharmacist in charge or an appropriate designee shall:

(1) be responsible for establishing and carrying out a performance improvement program as defined in section 1 of this rule; and

(2) develop or be responsible for development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-4)

856 IAC 1-28.1-5 Policies and procedures manual
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 5. (a) The pharmacist in charge shall develop or be responsible for the development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(b) The manual required in this section shall be available for inspection by a member of the board or its representative.

(c) The policies and procedures manual shall contain, at a minimum, the following:

(1) Provisions for a continuous quality improvement committee that shall be comprised of staff members of the pharmacy, including, but not necessarily limited to, the following:

(A) Pharmacists.

(B) Pharmacist interns or externs.

(C) Pharmacy technicians.

(D) Clerical or support staff.

(E) Other persons deemed necessary by the qualifying pharmacist.

(2) Provisions for the pharmacist in charge or designee to ensure that the committee conducts a review of quality related events at least every three (3) months.

(3) A process to record, measure, assess, and improve quality of patient care.

(4) The procedure for reviewing quality related or sentinel events.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-5)

856 IAC 1-28.1-6 Personnel
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 6. The qualifying pharmacist and/or the pharmacist in charge shall develop and implement, or cause to be developed and implemented, policies and procedures that specify duties to be performed by pharmacy technicians and other ancillary personnel.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-6)

856 IAC 1-28.1-7 Pharmacist's duties
Authority: IC 26-26-13-4
Affected: IC 16-42-19-3; IC 25-26-13; IC 25-26-16

Sec. 7. (a) Pursuant to authority granted in IC 25-26-13-2 and IC 25-26-13-31, the duties of the pharmacists practicing in the institutional pharmacy include, but are not limited to, the requirements in this section.

(b) The pharmacist practicing in an institutional pharmacy shall, at a minimum, do the following:

(1) Obtain and maintain patient drug histories and drug profiles.

(2) Perform drug evaluations, drug utilization review, drug regimen review, and drug therapy management under protocol approved by the medical staff of the institution and authorized by IC 25-26-16.

(3) Interpret the drug order written by a practitioner in or transmitted to an institutional facility and either received in or subsequently transmitted to the pharmacy.

(4) Be responsible for checking all drug orders within a maximum of twenty-four (24) hours, including those written during periods when the pharmacy is closed and orders are filled from sources, including emergency kits, drug cabinets, or the pharmacy as authorized under section 8(c) of this rule.

(5) Be responsible for drug product selection of the item that will be used to fill the drug order that may be established either by policy or formulary pursuant to the institution's pharmacy and therapeutics committee or related committee.

(6) Be responsible for determining the legality, completeness, and appropriateness of the drug order and product pursuant to IC 16-42-19-3.

(7) Participate in drug or drug-related research.

(8) Provide counseling, advising, and education of patients, patients' care givers, and health care providers and professionals on issues regarding drugs or drug therapy.

(9) Compound, label, administer, and dispense drugs or devices.

(10) Assess, record, and report quality related events as defined in this rule.

(11) Be responsible for storage and distribution of drugs and devices.

(12) Provide documentation in the medical record of the recommendations made related to the patient's therapeutic response to medication.

(13) Any other duties that shall from time to time be necessary for the proper operation of the institutional pharmacy.

(c) The consultant pharmacist shall, in addition to the duties in subsection (b), provide cognitive services as defined in this rule, including, at a minimum, the following:

(1) Drug regimen reviews as defined in IC 25-26-13-2.

(2) Offer advice and counsel to other health care providers as deemed appropriate regarding the pharmaceutical care of the patient.

(3) Develop or assist in the development of policies and procedures for the legal, safe, and effective means of handling, storing, and disposing of drugs and devices.

(4) Be responsible for assuring the safe and appropriate receipt, labeling, storage, and disposal of all drugs placed outside the pharmacy licensed area in emergency drug kits or other storage devices as authorized by law or rule.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-7)

856 IAC 1-28.1-8 Absence of pharmacist
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 8. (a) During such times as an institutional pharmacy is closed and unattended by a pharmacist, the drugs may be obtained for patient use as outlined in this section.

(b) Cabinets, including mechanical storage devices for dispensing drugs, are locked or secured enclosures located outside the pharmacy licensed area, to which only specifically authorized personnel may obtain access by key, combination, or security code, password, or other method of positively identifying an individual, and are sufficiently secure to deny access to unauthorized persons. The qualifying pharmacist and/or pharmacist in charge shall, in conjunction with the appropriate committee of the institutional facility, develop inventory

listings of the drugs to be included in such cabinets and shall ensure the following:

(1) Such listed drugs, properly labeled, are available therein.

(2) Only prepackaged drugs (meaning that no repackaging is required at the time of removal for an individual patient's use) are available therein, in amounts sufficient for immediate therapeutic requirements for a period not to exceed twenty-four (24) hours.

(3) When drugs are used, a record is made to include a written physician's order or accountability record.

(4) All drugs therein are reviewed by a pharmacist upon return to duty, not to exceed twenty-four (24) hours.

(5) There are written policies, procedures, and forms established to implement the requirements of this subsection.

(c) Whenever any drug is not available from floor supplies or cabinets, as defined in this section, and such drug is required to treat the immediate needs of a patient, such drug may be obtained from the pharmacy in accordance with the requirements of this subsection. One (1) supervisory licensed nurse in any given shift may have access to the pharmacy and may remove drugs therefrom. The qualifying pharmacist shall require that the removal of any drug from the pharmacy by an authorized nurse be recorded on a suitable form, which includes the name of the drug, strength, amount, date, time, and signature of nurse, and that a copy of the order shall be left with the form.

(d) Requirements for hospital emergency drug boxes, drug carts, emergency kits, emergency drug kits, crash carts, drug kits, or other storage method for emergency drugs are as follows:

(1) Pharmacy policy and procedures shall assure the:

(A) availability;

(B) control; and

(C) security;

of emergency drug carts, drug kits, or drug boxes in the pharmacy and patient care areas.

(2) Procedures shall include the following:

(A) Determination of drugs and quantities of drugs to be included.

(B) Labeling for expiration date.

(C) Process for restocking the cart, kit, or box.

(D) Security measures to prevent unauthorized access.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-8)

856 IAC 1-28.1-9 Emergency drug kits from Type III and Type VI pharmacies

Authority: IC 26-26-13-4

Affected: IC 25-26-13-17; IC 35-38

Sec. 9. (a) Emergency drug kits supplied by pharmacies with a Type III or Type VI permit shall be in compliance with this section.

(b) All drugs in the emergency kit shall be provided and owned by a single supplying pharmacy.

(c) All drugs in the emergency drug kit shall be selected and approved by a committee whose membership includes, at a minimum, the following:

(1) The facility's consultant pharmacist.

(2) A licensed nurse.

(3) A physician (medical doctor or doctor of osteopathy).

(4) The facility administrator.

(d) The selection process must identify drugs and quantities thereof in the emergency drug kit.

(e) The lists of drugs and quantities included in the emergency drug kit shall be reviewed as required periodically, but no less often than yearly.

(f) Labeling as follows:

(1) The exterior labeling of the emergency drug kit as described in this subsection shall contain, at a minimum, the following:

(A) Drug name (trade name, generic name, or active ingredients).

(B) Drug strength or size, if any.

(C) Quantity included therein.

(D) Expiration date of the kit as defined in this section.

(2) All drugs contained in the emergency drug kit as described in this section shall be labeled, at a minimum, with the following:

(A) Drug name (trade name, generic name, or active ingredients).

(B) Drug strength or size, if applicable.

(C) Name of the manufacturer, packer, or distributor.

(D) Lot number.

(E) Expiration date.

(g) The expiration date of the emergency drug kit, as required in subsection (f)(1)(D) shall be the earliest date of expiration of any of the drugs included in the kit at any time.

(h) All emergency kits subject to this subsection:

(1) shall be stored in a secure area, suitable for the prevention of unauthorized access to or diversion of the drugs therein;

(2) if controlled substances, as defined in IC 35-38, are stored in such a manner as to facilitate periodic reconciliation by the facility nursing staff, that reconciliation shall be recorded in an appropriate manner as determined by the committee described under this section; and

(3) all controlled substances contained in emergency drug kits shall remain the property of the supplying pharmacy and as such shall be included in the pharmacy's biennial inventory as required by 21 CFR 1303.04 and 21 CFR 1301.11.

(i) The nurse responsible for removing drugs from an emergency drug kit shall record or cause to be recorded, in a manner designated under subsection (h)(2), the following minimum information:

(1) Name of the patient.

(2) Name of the drug.

(3) Strength of the drug.

(4) Quantity removed.

(5) Date of removal.

(6) Time of removal.

(j) Removal of a controlled substance in Schedule II pursuant to an oral authorization from a practitioner shall be documented and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-7 regarding prescription requirements for controlled substances in Schedule II.

(k) Removal of a controlled substance in Schedule III, IV, or V, pursuant to an oral authorization from a practitioner shall be documented and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-12.

(l) Whenever an emergency kit is opened, for any reason, the supplying pharmacy shall be notified in a timely manner and the pharmacy shall restock if necessary, and reseal the kit promptly so as to prevent risk of harm to patients of the facility.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-9)

856 IAC 1-28.1-10 Security

Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 10. The pharmacy shall be capable of being secured against entry by key, combination, code, password, or other method developed that can positively identify an individual so as to prevent access by unauthorized personnel.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-10)

856 IAC 1-28.1-11 Performance improvement events, sentinel events, corrective and avoidance measures, review, records, and documentation
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 11. (a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program, assure or be responsible for assuring that data are collected to:
(1) monitor the stability of existing medication use processes;
(2) identify opportunities for improvement; and
(3) identify changes that will lead to and sustain improvement.

(b) Identification of quality related or sentinel event as defined in section 1 of this rule shall be cause for:
(1) an intensive analysis of causal factors involved in the event; and
(2) plans for corrective actions.

(c) Records of all processes, analysis, and corrective measures instituted involving such pharmacy quality related or sentinel event shall be maintained for a period of not less than two (2) years.

(d) The committee created under section 5(c)(1) of this rule shall, at a minimum, consider the effects on quality of the pharmacy system due to the following:
(1) Staffing levels of both professional and technical personnel.
(2) Workflow.
(3) Use of technology.
(e) Requirements for documentation of performance improvement monitoring of medication use processes, confidentiality of records, summarization, and examination by the board shall be as follows:
(1) Each quality related or sentinel event that occurs, or is alleged to have occurred, as the result of activities involving pharmacy operations, shall be documented in a written or electronic storage record created solely for that purpose.
(2) The quality related or sentinel event shall be:
(A) initially documented by the pharmacist to whom it is first described; and
(B) recorded on the same day of its having been so described to the pharmacist.
(3) Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event.
(4) The pharmacist in charge shall summarize, or cause to be summarized, efforts to improve the medication use process on a semiannual basis.
(5) No patient names or employee names shall be included in this summary report.
(6) This report shall be maintained for a period of not less than two (2) years.
(7) The records created and maintained as a component of a pharmacy performance improvement program are confidential to the extent law permits. However, to assure compliance, the board or its representative may review the policies and procedures manual and a summarization of events described in subsection (b).
(Indiana Board of Pharmacy; 856 IAC 1-28.1-11)

856 IAC 1-28.1-12 Drug distribution, storage, and accountability
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 12. (a) All drugs and devices in pharmacies located within institutions shall be obtained and used in accordance with written policies and procedures that have been prepared or approved by the qualifying pharmacist or pharmacist in charge, and the medical staff who explain the:
(1) selection;
(2) distribution;
(3) storage; and
(4) safe and effective use of:
(A) drugs;
(B) new drugs;
(C) investigational new drugs; and
(D) devices;
in the facility.

(b) The pharmacist in charge of the pharmacy located within an institution shall be responsible for the following:
(1) The safe and efficient:
(A) distribution;
(B) control;
(C) storage; and
(D) accountability;
for all drugs and devices.
(2) The compliance with all applicable Indiana and federal laws and rules.

(c) Labeling requirements are as follows:
(1) All drugs, other than unit-of-use packages, dispensed by an institutional pharmacy, intended for use within the facility, shall be distributed in appropriate containers and adequately labeled so as to identify, at a minimum, the following:
(A) Patient identification.
(B) Brand name or generic name, or both.
(C) Strength if applicable.
(D) Route of administration.
(E) Quantity.
(F) Pharmacist's initials.
(G) Location of the patient within the institution.
(2) Unit-of-use packages shall contain information to adequately label them, at a minimum, as follows:
(A) Drug name (brand or generic, or both).
(B) Strength, if applicable.
(C) Control number and/or expiration date.
(3) All drugs dispensed by an institutional pharmacy to patients about to be discharged, or temporarily discharged, from institutions with Type III or Type IV permits, shall be labeled with the following minimum information:
(A) Name, address, and telephone number of the institutional pharmacy.
(B) Date and identifying serial number.
(C) Name of patient.
(D) Name of drug and strength (if applicable).
(E) Directions for use by the patient and route of administration.
(F) Name of prescribing practitioner.
(G) Precautionary information if any contained in the prescription.

(d) Requirements for the disposition of discontinued or recalled drugs are as follows:

(1) The qualifying pharmacist or pharmacist in charge shall be responsible for the development and implementation of policies and procedures for the return to the pharmacy of drugs and containers that are:

(A) discontinued, outdated, or recalled; or

(B) in containers with worn, illegible, or missing labels;

for proper disposition.

(2) The qualifying pharmacist or pharmacist in charge or his or her designee shall make proper disposition of such drugs at the storage site.

(e) The qualifying pharmacist or pharmacist in charge shall ensure that drugs are dispensed from the institutional pharmacy only upon authorized practitioner's:

(1) written orders;

(2) direct copies;

(3) facsimiles thereof; or

(4) electronically transmitted by other means and printed or displayed appropriately.

(f) Accountability requirements are as follows:

(1) The qualifying pharmacist or pharmacist in charge of an institutional pharmacy shall ensure that policies and procedures documenting the trail of:

(A) controlled substances; and

(B) such other drugs as may be specified by the appropriate committee of the institutional facility, from ordering and receiving by the pharmacy through administration or wastage of drug at the patient level.

(2) The qualifying pharmacist or pharmacist in charge shall be responsible for review of this process on a continual basis by review of:

(A) proofs-of-use documentation; or

(B) other electronic documentation methodology.

(3) At a minimum, the documentation process shall be able to identify the following:

(A) The name of the drug.

(B) The dose.

(C) The patient's name.

(D) The date and time of administration to the patient.

(E) The identification of the individual administering.

(F) The record of aliquot portion destroyed, if any, and identification of witness.

(g) All records and reports that are required for pharmacy functions shall be maintained according to policies and procedures developed within the institution with the approval of the pharmacist in charge, for a period of not less than two (2) years.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-12)

856 IAC 1-28.1-13 Drug self-administration
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 13. Self-administration of drugs by patients of an institutional facility shall be permitted only if such use is specifically authorized by the treating or ordering physician and:

(1) the patient's knowledge of self-administration has been evaluated; or

(2) the patient has received training in the proper manner of self-administration:

(A) by a pharmacist; or

(B) according to hospital policy; and

(3) there is no risk of harm to the patient.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-13)

856 IAC 1-28.1-14 Patient's own medication
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 14. (a) An institutional pharmacy is prohibited from accepting and dispensing drugs that are brought into the institution by the patient, even if intended for use by that same patient. However, use of the patient's own medication may be permitted if:

(1) the patient or the patient's representative may maintain the patient's own medication:

(A) at the bedside; or

(B) for drugs with special storage requirements, including, but not limited to, refrigeration in an appropriate storage area in the patient care area under control of nursing personnel for appropriate administration to that patient only; and

(2) the nurses in charge of that patient's care shall witness the administration and maintain records of such use.

(b) If the patient or the patient's representative brings in medication part or all of which is still present at such time a patient expires, those drugs shall be delivered to the institutional pharmacy for appropriate destruction. Such drugs may not be turned over to the patient's representatives. This rule shall be made clear to the parties involved prior to the permission to use such medication. Patients who are discharged shall take with them their own medications brought to the institution under the terms of this section.

(c) In the event the patient is discharged and leaves drugs brought in under this section, either deliberately or inadvertently, such drugs shall be documented and stored at the appropriate nursing location for a maximum of seven (7) calendar days. If not claimed by the patient or the patient's agent within those seven (7) calendar days, the drugs so stored shall be destroyed as described in subsection (b).

(Indiana Board of Pharmacy; 856 IAC 1-28.1-14)

856 IAC 1-28.1-15 Inspections
Authority: IC 26-26-13-4
Affected: IC 16-42-3-3; IC 25-26-13-17

Sec. 15. The qualifying pharmacist or pharmacist in charge shall be responsible for the timely inspection of all areas where drugs are stored, used, or administered. The inspection can be carried out by qualified designee and appropriate records kept. The inspection shall verify, at a minimum, the following:

(1) Disinfectants and drugs solely for nontherapeutic external use are stored separately and apart from drugs for internal use or injection.

(2) Drugs requiring special storage conditions are appropriately stored to assure the drugs are not adulterated as described in IC 16-42-3-3.

(3) Drugs subject to deterioration are removed from any accessible location prior to the expiration date (manufacturer's or other such as required under 856 IAC 1-21) and disposed of appropriately.

(4) Emergency drugs designated by the institution are in adequate supply and are properly stored in the institution.

(5) All necessary and required security and storage standards are met.

(6) All pharmacy-related policies and procedures of the institution are complied with.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-15)

Rule 29. Electronic Data Processing of Prescriptions

856 IAC 1-29-1 Approval of electronic data processing system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) No electronic data processing system may be used by a pharmacist pursuant to a Type I, Type III, and Type VI pharmacy permit as an alternative to his or her recordation of prescription information unless that system has been approved by the Indiana board of pharmacy (board).

(b) No electronic data processing system may be used by a pharmacist as an alternative to his recordation of information directly on the original prescription pursuant to IC 25-26-13-25(c), without the approval of the board, and such an electronic data processing system does not qualify for approval unless it satisfies at a minimum the requirements found in this rule. Any such system must be approved by the board before initial installation in Indiana. Any pharmacy installing such a system must make a written request to the board for approval. Approval is subject to withdrawal for cause so that the pharmacist must in such a case discontinue use of the system as an alternative. (Indiana Board of Pharmacy; 856 IAC 1-29-1; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2543; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)

856 IAC 1-29-2 On-line retrieval and printout capabilities; data requirements; discontinuance of system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Any such proposed computerized system must provide on-line retrieval (via visual display device or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include:

(1) prescription number;

(2) date of issuance of the original prescription order by the prescriber;

(3) full name and address of the patient;

(4) name and address of prescriber;

(5) DEA number of prescriber when drug prescribed is controlled substance;

(6) the name, strength (if applicable), dosage form, and quantity of medication originally dispensed;

(7) total number of refills authorized by prescriber.

(b) In addition to the information contained in subsection (a) above, the following information shall be maintained for each filling:

(1) date dispensed;

(2) quantity dispensed, if different from the quantity prescribed;

(3) identification of dispensing pharmacist;

(4) adequate information to determine the number of authorized refills remaining.

(c) The system shall be able to produce a complete printout of current prescription status that would provide all necessary refill information for use in the event that the pharmacy wishes to discontinue use of the computer system. The report shall list all currently refillable prescriptions in sequence by prescription number. The following information shall be included:

(1) prescription number;

(2) date dispensed, quantity, and pharmacist's identification;

(3) the number of refills presently remaining and the amount owed, if any, from any partial refills.

(Indiana Board of Pharmacy; 856 IAC 1-29-2; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-29-3 Hard-copy of daily dispensing; verification and retention; back-up capability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 3. (a) A pharmacy using an electronic data processing system must provide a separate hard-copy printout of prescription order and refill data for each day's dispensing or other board approved uniformly maintained readily retrievable system. This hard-copy printout or other board approved system shall include the following:

(1) prescription number;

(2) date of dispensing;

(3) patient name;

(4) drug and strength (if applicable);

(5) quantity dispensed;

(6) prescriber identification;

(7) pharmacist identification;

(8) refill status;

(9) controlled drug schedule identification.

(b) The dispensing pharmacist must verify that the data is correct to the best of his knowledge and date and sign the document or log book in the same manner as he would sign a check or legal document.

(c) This documentation shall be maintained for a period of five (5) years from the dispensing date. The daily hard-copy printout may be replaced with a monthly printout or other permanent documentation containing the same information.

(d) Each system must have the capability of informational back-up and such documentation must be stored in a secure location. (Indiana Board of Pharmacy; 856 IAC 1-29-3; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-29-4 Auxiliary system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 4. In the event that a pharmacy which employs such an electronic data processing system experiences system down time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line service. However, nothing in this section shall preclude a pharmacist from using his professional judgment to benefit the health of the patient. (Indiana Board of Pharmacy; 856 IAC 1-29-4; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-29-5 Safeguards

Authority: IC 25-26-13-4
Affected: IC 25-26-13-15; IC 25-26-13-25

Sec. 5. When utilizing electronic data processing systems, pharmacists shall comply with IC 25-26-13-15. (Indiana Board of Pharmacy; 856 IAC 1-29-5; filed Aug 16, 1984, 3:55 pm: 7 IR 2545; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-29-6 Data entry; supervision

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 6. When electronic data processing equipment is utilized in any pharmacy, input of drug information shall be performed by a pharmacist or under the immediate and personal supervision of a pharmacist. The pharmacist must certify the accuracy of the information entered and verify the prescription order. (Indiana Board of Pharmacy; 856 IAC 1-29-6; filed Aug 16, 1984, 3:55 pm: 7 IR 2545; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-29-7 Existing systems; compliance date (Repealed)

856 IAC 1-29-8 Transfer of prescriptions between pharmacies (Repealed)

856 IAC 1-29-9 Applicability of rule
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 9. This rule applies to pharmacies with Type I, Type III, Type IV, and Type VI permits. (Indiana Board of Pharmacy; 856 IAC 1-29-9; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2545; filed Mar 8, 1989, 10:00 a.m.: 12 IR 1634; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed Sep 21, 1992, 9:00 a.m.: 16 IR 724; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 30. Sterile Pharmaceuticals; Preparation and Dispensing

856 IAC 1-30-1 Purpose
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 1. The purpose of this rule is to provide standards for the preparation, labeling, and distribution of sterile pharmaceutical products by licensed pharmacists, pursuant to a drug order or prescription. (Indiana Board of Pharmacy; 856 IAC 1-30-1; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-2 “Biological safety cabinet” defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 2. As used in this rule, “biological safety cabinet” means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment. (Indiana Board of Pharmacy; 856 IAC 1-30-2; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-3 “Class 100 environment” defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 3. As used in this rule, “Class 100 environment” means an atmospheric environment which contains less than one hundred (100) particles five-tenths (0.5) microns in diameter per cubic foot of air. (Indiana Board of Pharmacy; 856 IAC 1-30-3; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-4 “Cytotoxic” defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4. As used in this rule, “cytotoxic” means a pharmaceutical that has the capability of killing living human cells. (Indiana Board of Pharmacy; 856 IAC 1-30-4; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-5 “Qualified pharmacist” defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 5. As used in this rule, “qualifying pharmacist' means a licensed pharmacist, identified in the policy and procedure manual, required by section 7 of this rule, as responsible for the preparation of the sterile pharmaceuticals, in compliance with the policy and procedure manual and the applicable laws governing the practice of pharmacy in Indiana. (Indiana Board of Pharmacy; 856 IAC 1-30-5; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)

856 IAC 1-30-6 “Sterile pharmaceutical” defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 6. As used in this rule, “sterile pharmaceutical” means a dosage form of a drug, free from living micro-organisms. (Indiana Board of Pharmacy; 856 IAC 1-30-6; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-7 Policy and procedure manual
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 7. Each pharmacy preparing and dispensing sterile pharmaceuticals shall maintain a policy and procedure manual relating to sterile products as part of the pharmacy policy and procedure manual or as a separate policy and procedure manual. This manual shall be available at the pharmacy for inspection by the board or its designated inspector. The manual shall be reviewed annually by the pharmacist-in-charge and revised if needed. The manual shall include the name of the pharmacist-in-charge of the preparation of sterile pharmaceuticals and policies and procedures for the following:

(1) Clinical services provided.

(2) The handling, storage, disposal, and clean-up of accidental spills of cytotoxic drugs, if they are prepared.

(3) Disposal of unused supplies and drugs.

(4) Drug destruction and returns.

(5) Drug dispensing.

(6) Drug labeling and relabeling.

(7) Drug storage.

(8) Duties and qualifications for professional and nonprofessional staff.

(9) Equipment.

(10) Handling of infectious wastes, if drug products or administration devices are returned to the pharmacy after administration in the case of home administration.

(11) Infusion devices and drug delivery systems, if utilized.

(12) Investigational drugs, if dispensed.

(13) Quality assurance procedures to include the following:

(A) Recall procedures.

(B) Storage and expiration dating.

(C) Educational procedures for professional staff, nonprofessional staff, and patient, if needed, in the case of home administration.

(D) Sterile procedures to include monitoring the temperature of the refrigerator, routine maintenance, and report of hood certification.

(E) Sterility testing or monitoring, if employed, in the case of routine bulk compounding from nonsterile chemicals.

(14) Reference manuals.

(15) Sterile product preparation procedures.

(Indiana Board of Pharmacy; 856 IAC 1-30-7; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1018, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-8 Physical requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 8. (a) A licensed pharmacy preparing sterile pharmaceuticals shall have a designated area for preparing compounded, sterile pharmaceuticals. The designated area shall be restricted to only those personnel authorized for the preparation of sterile pharmaceuticals. This area may be in a separate room or in a portion of a larger room. The area cannot be a warehouse or stockroom setting, and must be free of dust and dirt.

(b) The designated preparation area shall be used only for the preparation of sterile pharmaceutical products and related functions.

(c) The licensed pharmacy preparing sterile pharmaceutical products shall have the following equipment:

(1) An environmental control device capable of maintaining at least a Class 100 environment in the work space where critical objects are exposed and critical activities are performed. Examples of appropriate devices include laminar airflow hood and zonal laminar flow of high efficiency particulate air (HEPA) filtered air.

(2) A sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding.

(3) Disposal containers for used needles, syringes, gowns, gloves, etc., and, if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients.

(4) Environmental controls including biohazard cabinetry when cytotoxic drug products are prepared.

(5) A refrigerator with a thermometer.

(d) The licensed pharmacy preparing sterile pharmaceuticals shall include the following supplies:

(1) Disposable needles, syringes, and other supplies needed for aseptic admixture.

(2) Disinfectant cleaning solutions.

(3) Hand washing agent with antibacterial action.

(4) Disposable towels or wipes.

(5) Filters and filtration equipment, if utilized.

(6) A cytotoxic drug spill kit shall be available in the facility, if cytotoxic drugs are prepared.

(7) Disposable gowns and gloves.

(e) No one may have access to the pharmacy in the absence of the pharmacist, except as stated in 856 IAC 1-28-7.

(f) A pharmacy preparing sterile pharmaceuticals shall have in its reference library:

(1) the Handbook on Injectable Drugs, published by the American Society of Hospital Pharmacists (ASHP), 4630 Montgomery Avenue, Bethesda, Maryland 20814;

(2) the King's Guide to Parenteral Admixtures, published by Pacemarq Inc., 11701 Borman Drive, St. Louis, Missouri 63146; or

(3) other electronic data base for determining mixing and administration guidelines and drug incompatibilities;

in addition to other publications as required in 856 IAC 1-6-2.

(g) If the pharmacy is handling or preparing cytotoxic drugs, the pharmacy shall have a copy of Occupational Safety and Health Administration requirements for handling cytotoxic drugs as published in Occupational Safety and Health Administration Publication 8-1.1, Office of Occupational Medicine, Directorate of Technical Support, Occupational Safety and Health Administration, U.S. Department of Labor. (Indiana Board of Pharmacy; 856 IAC 1-30-8; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1018, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; errata filed Mar 17, 1992, 10:20 a.m.: 15 IR 1394; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-9 Personnel
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 9. (a) Each pharmacist engaged in preparing sterile pharmaceuticals must be trained in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. Documentation of such training or experience shall be made available for inspection by the board or its representatives.

(b) The qualifying pharmacist shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all sterile pharmaceuticals.

(c) The qualifying pharmacist shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and quality assurance programs. (Indiana Board of Pharmacy; 856 IAC 1-30-9; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)

856 IAC 1-30-10 Support personnel
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 10. (a) The pharmacist may be assisted by support personnel in compliance with IC 25-26-13-18(a)(4). Such personnel shall have specialized training in the preparation of sterile pharmaceuticals and shall work under the supervision of a licensed pharmacist. The training provided to these personnel shall be described in writing. The duties and responsibilities of supportive personnel must be consistent with their training and experience.

(b) This section is not to preclude other licensed health care professionals, as allowed by law, may also prepare sterile pharmaceuticals when there is an immediate need, or when the preparation in a pharmacy is not practical. (Indiana Board of Pharmacy; 856 IAC 1-30-10; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-11 Staffing
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 11. A pharmacist shall be accessible at all times to respond to patients' and other health professionals' questions and needs. (Indiana Board of Pharmacy; 856 IAC 1-30-11; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with

the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-12 Profile or medication record system
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 12. A pharmacy-generated profile or medication record system for sterile pharmaceuticals administered to patients, except for those inpatients in an institutional facility, as defined in 856 IAC 1-28-1(a), holding a Type II pharmacy permit, shall be maintained separately from the prescription file. The patient profile or medication record system shall contain at a minimum the following:

(1) Patient's name, date of birth or age, weight, and sex.

(2) Sterile pharmaceutical products dispensed.

(3) Drug content and quantity.

(4) Directions for the patient, if administered outside the facility.

(5) Identification of the dispensing pharmacist and other authorized personnel responsible for preparing the sterile pharmaceutical.

(6) Other drug therapy information, if applicable.

(7) Known or suspected drug sensitivities and allergies of the patient to drugs and foods, if applicable.

(8) Primary diagnosis and chronic conditions if the sterile pharmaceutical is administered outside the facility.

(Indiana Board of Pharmacy; 856 IAC 1-30-12; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-13 Labeling
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 13. (a) Each sterile pharmaceutical product dispensed to a patient shall be labeled with the following:

(1) Date of preparation by the pharmacy.

(2) Patient name and bed number, if an institutionalized patient.

(3) Name of each drug in the preparation, strength, and amount.

(4) Expiration date of the preparation, including time, if applicable.

(5) Identity of the pharmacist compounding and dispensing the sterile pharmaceutical, and identity of other authorized personnel preparing the product, if applicable.

(6) Other information required by the dispensing pharmacy regarding storage requirements or special warnings.

(b) In addition, if the patient residing at home or outside the facility where the sterile pharmaceutical is prepared, the following labeling requirements apply:

(1) Identifying prescription number.

(2) Prescriber's full name.

(3) Name, address, and telephone number of the licensed pharmacy.

(4) Directions for use shall be provided, either on the label or by other written instructions, including infusion rate and date and time of administration.

(Indiana Board of Pharmacy; 856 IAC 1-30-13; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; errata filed Mar 17, 1992, 10:20 a.m.: 15 IR 1394; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)

856 IAC 1-30-14 Records and reports
Authority: IC 25-26-13-4
Affected: IC 25-26-13-15; IC 25-26-13-18

Sec. 14. (a) The qualifying pharmacist shall be responsible for such records and reports as required to ensure the patient's health, safety, and welfare. Such records shall be readily available and maintained for two (2) years from the date of issuance of the prescription or drug order and be subject to inspection by the Indiana board of pharmacy or its designated inspector. These records shall include the following:

(1) Patient profile or medication record system.

(2) Policy and procedure manual.

(3) Training manuals.

(4) Policies and procedures for disposal of cytotoxic waste, when applicable.

(b) Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this

information shall be in accordance with IC 25-26-13-15. (Indiana Board of Pharmacy; 856 IAC 1-30-14; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)

856 IAC 1-30-15 Disposal of infectious waste
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 15. The qualifying pharmacist is responsible for assuring that there is a system for the disposal of infectious waste returned from outside the facility in a manner consistent with the protection of the public's health and safety and in compliance with applicable state and federal law. (Indiana Board of Pharmacy; 856 IAC 1-30-15; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)

856 IAC 1-30-16 Emergency kit
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 16. When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy may supply the nurse with emergency drugs, if the treating physician has authorized the use of such drugs by a protocol, for use in an emergency situation, e.g., anaphylactic shock. (Indiana Board of Pharmacy; 856 IAC 1-30-16; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-17 Cytotoxic drugs
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 17. The following additional requirements are necessary to ensure the protection of the personnel involved in those licensed pharmacies that prepare cytotoxic drugs:

(1) All cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet.

(2) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include disposable gloves and gowns with tight cuffs.

(3) Appropriate safety and special handling techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(4) Procedures for disposal of cytotoxic waste shall be specified within the policy and procedure manual as required by section 7 of this rule.

(5) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and included in the policy and procedure manual.

(6) Cytotoxic agents shall be properly labeled to identify the need for caution in handling, e.g., "Chemotherapy-Dispose of Properly". If shipped, the outer container must also be properly labeled with the same cautionary statement.

(Indiana Board of Pharmacy; 856 IAC 1-30-17; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-18 Quality assurance
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 18. (a) The designated qualifying pharmacist shall conduct a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. Samples of finished products shall be examined, or other continuous monitoring methods shall be used to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting their specifications. Quality assurance procedures shall include the following:

(1) Recall procedures for compounded sterile pharmaceuticals.

(2) Storage and dating for compounded sterile pharmaceuticals.

(3) Sterile procedures, including the following:

(A) Monitoring the temperature of the refrigerator.

(B) Routine maintenance.

(C) Report of laminar flow hood certification.

(4) Written documentation of periodic hood cleaning.

(b) All biological safety cabinets and Class 100 environments shall be certified by an independent contractor or facility specialist as meeting Federal Standard 209B or National Sanitation Foundation Standard 49, as referenced in section 2 of this rule, for operational efficiency. Such certification shall be performed at least annually. Records documenting certification shall be maintained for a period of not less than two (2) years.

(c) Prefilters for the clean air source shall be replaced or cleaned as applicable on a regular basis and the replacement or cleaning date documented.

(d) A vertical flow Class II biological safety cabinet may be used to compound any sterile pharmaceutical product; however, it must be thoroughly cleaned between each use for cytotoxic and noncytotoxic drug compounding.

(e) If manufacturing of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing, as referenced in Remington's Pharmaceutical Sciences, published by Mack Publishing Company, Easton, Pennsylvania 18042, or other Federal Drug Administration approved testing methods, must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter, microbial contamination, and testing for pyrogens. This does not preclude the extemporaneous compounding of certain sterile pharmaceuticals.

(f) There shall be written justification of the chosen expiration dates for compounded parenteral products documented in the policy and procedure manual.

(g) There shall be documentation of quality assurance audits at planned intervals, including infection control and sterile technique audits. (Indiana Board of Pharmacy; 856 IAC 1-30-18; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1021, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)

Rule 31. Facsimile Machines

856 IAC 1-31-1 "Facsimile machine" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 1. As used in this rule, "facsimile machine" means a machine that electronically transmits exact images through connection with a telephone network. (Indiana Board of Pharmacy; 856 IAC 1-31-1; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-31-2 Use of a facsimile machine to electronically transmit a prescription or drug order
Authority: IC 25-26-13-4
Affected: IC 25-1-9; IC 25-26-13

Sec. 2. Prescription or drug orders for legend drugs may be transmitted by facsimile machine from an authorized prescribing practitioner to a pharmacy under the following restrictions:

(1) The original prescription or order transmitted by facsimile machine contains:

(A) all information required under IC 25-26-13-2;

(B) the name and address of the pharmacy to which the prescription or drug order is being transmitted; and

(C) the name of the person transmitting the prescription or drug order.

(2) A statement that the prescription is valid only if transmitted by facsimile machine is included on the face of the original prescription or drug order.

(3) Actual transmission is done by or under the direct supervision of the authorized prescribing practitioner or by an authorized agent.

(4) A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's authorized agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in subdivision (5) or (6).

(5) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient in a private residence, long term care facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent by facsimile. The facsimile serves as the original written prescription, and it shall be maintained in accordance with IC 25-26-13-25.

(6) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II substance for a resident of a long term care facility licensed under 410 IAC 16.2-3.1 may be transmitted by the practitioner or the practitioner's authorized agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for the purpose of this subdivision, and it shall be maintained in accordance with IC 25-26-13-25.

(7) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II narcotic substance for a patient enrolled in a hospice program, inpatient or outpatient, certified by Medicare under Title XVIII or licensed by Indiana may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The

practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this subdivision and maintained in accordance with IC 25-26-13-25.

(8) A controlled substance prescription or drug order for a Schedule III, IV, or V controlled substance may be sent by facsimile machine and must be sent by the prescribing practitioner or an authorized agent.

(9) A facsimile machine transmitted copy of a prescription or drug order must produce a nonfading copy or be reduced to writing, either manually or via other processes, for example, photocopying, that produces a nonfading document. Proper notation on the file copy shall indicate that the prescription order was initially received via facsimile machine transmission.

(10) The receiving facsimile machine must be located in the prescription department of the pharmacy or in another nonpublic area of the pharmacy to protect patient/pharmacist/authorizing prescribing practitioner confidentiality and security as required by IC 25-26-13-15.

(11) Using facsimile equipment to circumvent documentation, authenticity, verification, or other standards of the profession of pharmacy will be considered professional incompetence under IC 25-1-9.

(Indiana Board of Pharmacy; 856 IAC 1-31-2; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; filed Aug 17, 1995, 8:30 a.m.: 19 IR 39; filed May 26, 2000, 8:52 a.m.: 23 IR 2502; filed May 10, 2001, 9:22 a.m.: 24 IR 3067; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 32. Transfer of Prescriptions Between Pharmacies

856 IAC 1-32-1 Applicability of rule

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. This rule governs the transfer of prescription information, either originally filled or previously

refilled, by one (1) pharmacy to another pharmacy for refills. (Indiana Board of Pharmacy; 856 IAC 1-32-1; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)

856 IAC 1-32-2 Noncontrolled and controlled substance prescription transfers

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Prescription information for legend drugs that are not controlled substances may be transferred at any time during the lifetime of the prescription up to one (1) year after the date of the original filling, or when the original number of authorized refills expires, whichever comes first.

(b) Except as limited by the requirement of subsection (a), prescriptions for legend drugs that are not controlled substances may be transferred any number of times.

(c) If any authorized refills remain, prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances may be transferred only once within six (6) months from the date the prescription was issued. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(d) Prescriptions for Schedule II controlled substances may not be transferred. (Indiana Board of Pharmacy; 856 IAC 1-32-2; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)

856 IAC 1-32-3 Patient's right to transfer prescriptions

Authority: IC 25-26-13-4
Affected: IC 25-26-13-16; IC 25-26-13-25

Sec. 3. A pharmacist may not legally refuse to transfer a patient's prescription or prescription information except when to do so would be against the professional judgment of the pharmacist in the manner provided for under IC 25-26-13-16. (Indiana Board of Pharmacy; 856 IAC 1-32-3; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)

856 IAC 1-32-4 Pharmacists' responsibilities

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 4. Transfer of prescription information under this rule must meet the following requirements:

(1) The transfer is communicated directly between two (2) licensed pharmacists or by suitable electronic device approved by the Indiana board of pharmacy, and the transferring pharmacist records the following information:

(A) Write the word "VOID" on the face of the invalidated prescription.

(B) Record on the reverse of the invalidated prescription, the name, address, and Drug Enforcement Administration registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription.

(C) Record the date of the transfer and the name of the pharmacist transferring the information.

(2) The pharmacist receiving the transferred prescription shall reduce to writing the following:

(A) Write the word "TRANSFER" on the face of the transferred prescription.

(B) Provide all information required to be on a prescription and include the following:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescriptions.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date of last refill, and, in the event the transfer is for the second or subsequent transfer of a substance that is a Schedule III, Schedule IV, or Schedule V controlled substance, the date and location of the previous refill.

(v) Pharmacy's name, address, Drug Enforcement Administration registration number, and original prescription number from which the prescription information was transferred.

(vi) Name of the transferor pharmacist.

(C) Both the original and transferred prescription must be maintained as required under IC 25-26-13-25.

(3) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

(Indiana Board of Pharmacy; 856 IAC 1-32-4; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)

Rule 33. Counseling

856 IAC 1-33-1 "Counseling" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 1. As used in this rule, "counseling" means effective communication, by a pharmacist, of information in order to improve therapeutic outcomes by maximizing the proper use of prescription medications and devices. (Indiana Board of Pharmacy; 856 IAC 1-33-1; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-33-2 Patient counseling requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-16

Sec. 2. (a) Upon the receipt of a prescription or upon the subsequent refilling of a prescription, and following a review of the patient's prescription medication profile, the pharmacist shall be responsible for the initiation of an offer to discuss matters (counsel) which, in the pharmacist's professional judgment, are significant to optimizing drug therapy. Depending upon the situation, these matters may include, but are not necessarily limited to, the following:

(1) The name and description of the medicine.

(2) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(3) Special directions and precautions.

(4) Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.

(5) Techniques for self-monitoring drug therapy.

(6) Proper storage.

(7) Prescription refill information.

(8) Action to be taken in the event of a missed dose.

(b) Counseling shall be in person, whenever practicable, or through access to a telephone service which is toll free for long distance calls, and be held with the patient, the patient's caregiver, or the patient's representative.

(c) Alternative forms of patient information may be used to supplement verbal counseling when appropriate. Examples include, written information leaflets, pictogram labels, and video programs. Nothing in this subsection shall be construed to mean that supplements may be a substitute for verbal counseling when verbal counseling is practicable.

(d) Nothing in this rule shall be construed as requiring a pharmacist to provide counseling when a patient refuses the offer to counsel. (Indiana Board of Pharmacy; 856 IAC 1-33-2; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-33-3 Patient profile requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 3. The pharmacist shall assure that prescription medication profiles are maintained for all patients receiving pharmaceutical care at that pharmacy. Within limits of reasonably available information, the pharmacy medication profile shall include the following:

(1) Name, address, telephone number, age or date of birth, and gender.

(2) Known drug allergies and adverse reactions.

(3) A list of current medications and relevant devices, either of which may relate to the patient's drug therapy.

(4) Known disease states.

(5) Any other information that, in the pharmacist's professional judgment, the pharmacist deems appropriate.

(6) Pharmacist's comments relevant to the individual's drug therapy.

(Indiana Board of Pharmacy; 856 IAC 1-33-3; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-33-4 Institutional patient exception
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 4. The requirements for patient counseling, as described in this rule, shall not apply to patients residing in institutional facilities in Indiana as defined under 856 IAC 1-28-1(a). (Indiana Board of Pharmacy; 856 IAC 1-33-4; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1177; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 34. Security Features for Prescriptions

856 IAC 1-34-1 Applicability
Authority: IC 35-48-7-8
Affected: IC 16-42-19-5

Sec. 1. This rule establishes minimum standards for security features for prescriptions issued by practitioners as described in IC 16-42-19-5. Practitioners licensed in Indiana must comply with this rule in order for their prescriptions to be accepted for filling in licensed Indiana pharmacies. (Indiana Board of Pharmacy; 856 IAC 1-34-1; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2782, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-34-2 Security feature requirements
Authority: IC 35-48-7-8
Affected: IC 16-42-19-5

Sec. 2. (a) All controlled substance prescriptions written by licensed Indiana practitioners, as defined by IC 16-42-19-5, must contain the following security features:

(1) A latent, repetitive “void” pattern screened at five percent (5%) in reflex blue must appear across the entire face of the document when the prescription is photocopied.

(2) There shall be a custom artificial watermark printed on the back side of the base paper so that it may only be seen at a forty-five (45) degree angle. The watermark shall consist of the words “Indiana Security Prescription”, appearing horizontally in a step-and-repeated format in five (5) lines on the back of the document using 12-point Helvetica bold type style.

(3) An opaque RX symbol must appear in the upper right-hand corner, one-eighth (_) of an inch from the top of the pad and five-sixteenths ($^5/_{16}$) of an inch from the right side of the pad. The symbol must be three-fourths (¾) inch in size and must disappear if the prescription copy is lightened.

(4) Six (6) quantity check-off boxes must be printed on the form and the following quantities must appear and the appropriate box be checked off for the prescription to be valid:

(A) 1–24
(B) 25–49
(C) 50–74
(D) 75–100
(E) 101–150
(F) 151 and over.

(5) No advertisements may appear on the front or back of the prescription blank.

(6) Logos, defined as a symbol utilized by an individual, professional practice, professional association, or hospital, may appear on the prescription blank. The upper left one (1) inch square of the prescription blank is reserved for the purpose of logos. Only logos, as defined by this subdivision, may appear on the prescription blank.

(7) Only one (1) prescription may be written per prescription blank. The following statement must be printed on the bottom of the pad: “Prescription is void if more than one (1) prescription is written per blank.”.

(8) Refill options that can be circled by the prescriber must appear below any logos and above the signature lines on the left side of the prescription blank in the following order:

Refill NR 1 2 3 4 5 Void after_____.

(9) Practitioner name and state issued professional license number must be preprinted, stamped, or manually printed on the prescription.

(10) All prescription blanks printed under this rule shall be four and one-fourth (4¼) inches high and five and one-half (5½) inches wide.

(b) Nothing in this rule shall prevent licensed Indiana practitioners from utilizing security paper prescriptions for the prescribing of any legend drug. (Indiana Board of Pharmacy; 856 IAC 1-34-2; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2782, eff Jan 1, 1996; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)

856 IAC 1-34-3 Preprinted controlled substance prohibition
Authority: IC 35-48-7-8
Affected: IC 35-48-2; IC 35-48-7

Sec. 3. The name of any controlled substance, as defined by IC 35-48-2, may not be preprinted on any prescription forms at any time before the prescription is being prepared and executed for presentation to the patient or the patient's agent. That includes, but is not limited to, such activities as typing prescriptions in anticipation of their need, and using a rubber stamp or other similar means which would accomplish the same end. Commercially printed forms containing names of controlled substances are also prohibited. (Indiana Board of Pharmacy; 856 IAC 1-34-3; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-34-4 Exemption
Authority: IC 35-48-7-8
Affected: IC 35-48-7

Sec. 4. Prescriptions utilized by pharmacists to record call-in prescriptions, transferred prescriptions, or facsimile prescriptions do not need to comply with this rule. (Indiana Board of Pharmacy; 856 IAC 1-34-4; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-34-5 Approval
Authority: IC 35-48-7-8
Affected: IC 35-48-7

Sec. 5. Printers wishing to supply prescription blanks to authorized recipients must obtain a template design from the board to use as a layout guide. Printers must also submit a preprint proof to the board for approval prior to any production of prescription blanks governed by this rule. (Indiana Board of Pharmacy; 856 IAC 1-34-5; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 35. Pharmacy Technicians

856 IAC 1-35-1 Purpose and scope
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) The board is responsible for establishing standards for the competent practice of pharmacy.

(b) The use of pharmacy technicians to assist the pharmacist with nondiscretionary functions associated with the practice of pharmacy enables the pharmacist to provide pharmaceutical care to the patient.

(c) Evolved pharmacy practice demands additional time for pharmacists to counsel individual patients regarding the proper use of drugs.

(d) Only pharmacists (licensed under IC 25-26-13-11), pharmacy interns and externs (as defined in IC 25-26-13-2 and registered under IC 25-26-13-10), and pharmacy technicians as described in this section shall be permitted to participate in the activities associated with a drug order or prescription preparation.

(e) A pharmacist shall not permit a pharmacy technician to participate in the activities associated with a drug order or prescription preparation unless the pharmacy technician meets the qualifications of this section. (Indiana Board of Pharmacy; 856 IAC 1-35-1; filed Aug 17, 1995, 8:30 a.m.: 19 IR 39; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-35-2 "Unlicensed person" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 2. (a) As used in this rule, "unlicensed person" means a pharmacy technician who, under the immediate and direct supervision of the pharmacist, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescriptions and drug orders.

(b) As used in subsection (a), "pharmacy technician" shall not include pharmacy intern/externs or other ancillary persons which include, but are not limited to:

(1) clerks;
(2) secretaries;
(3) cashiers; or
(4) delivery persons;

who may be present in the pharmacy. (Indiana Board of Pharmacy; 856 IAC 1-35-2; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-35-3 "Pharmaceutical care" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. As used in this rule, "pharmaceutical care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. (Indiana Board of Pharmacy; 856 IAC 1-35-3; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-35-4 Qualifications
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4. To be eligible to perform the functions and duties of a pharmacy technician, an individual must possess the following qualifications, which shall be ascertained and documented by the pharmacist that qualifies the pharmacy permit:

(1) The individual has not been convicted of a crime that has a direct bearing on the individual's ability to work with legend drugs or controlled substances.

(2) The individual must be a high school graduate or have successfully completed a General Education Development program.

(3) The individual must have successfully completed or be enrolled in one (1) of the following board approved programs:

(A) A board approved comprehensive curricular-based education and training program conducted by a pharmacy or educational organization.

(B) A technician training program utilized by the employer that includes specific training in the duties required to assist the pharmacist in the technical functions associated with the practice of pharmacy. The contents of the training program shall include, at a minimum, the following:

(i) Understanding of the duties and responsibilities of the technician and the pharmacist, including the standards of patient confidentiality and ethics governing pharmacy practice.

(ii) Tasks and technical skills, policies, and procedures related to the technician's position.

(iii) Working knowledge of pharmaceutical-medical terminology, abbreviations, and symbols commonly used in prescriptions and drug orders.

(iv) Working knowledge of the general storage, packaging, and labeling requirements of drugs, prescriptions, or drug orders.

(v) Ability to perform the arithmetic calculations required for the usual dosage determinations.

(vi) Working knowledge and understanding of the essential functions related to drug purchasing and inventory control.

(vii) The record keeping functions associated with prescriptions or drug orders.

(C) A record of the pharmacy technician training and education must be maintained in the pharmacy where the technician is employed and shall include the following:

(i) The name of the pharmacy technician.

(ii) The date of completion of the training program.

(iii) A copy of the training manual, if on-the-job training is used by the employer, or certificate of successful completion of another approved program, or other training program completed prior to employment.

(Indiana Board of Pharmacy; 856 IAC 1-35-4; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-35-5 Duties that a pharmacy technician may not perform

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 5. A pharmacy technician may perform many technical functions associated with the practice of pharmacy. However, even under the immediate and direct supervision of a pharmacist, the pharmacy technician is prohibited from performing the following functions:

(1) Any duty required by law, regulation, or rule to be performed by a pharmacist.

(2) The provision of advice or consultation with the prescriber or other licensed health care provider regarding the patient or the interpretation and application of information contained in the prescription or drug order, medical record, or patient profile.

(3) The provision of advice or consultation with the patient regarding the interpretation of the prescription or the application of information contained in the patient profile or medical record.

(4) Dispensing of prescription drug information to the patient as required in IC 25-26-13-4.

(5) Receipt of a verbal prescription, other than a refill approval or denial, from a prescriber.

(6) Final check on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including, but not limited to, accuracy of the:

(A) drug;

(B) strength; and

(C) labeling.

(Indiana Board of Pharmacy; 856 IAC 1-35-5; filed Aug 17, 1995, 8:30 a.m.: 19 IR 41; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-35-6 Provision of quality assurance; duties

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 6. (a) The pharmacist is responsible for the work performed by the pharmacy technician under the pharmacist's supervision. Therefore, a pharmacist employing a pharmacy technician shall establish written policies and procedures that describe in detail the means of providing supervisory oversight and continuous monitoring of the pharmacy technician's work performance.

(b) These policies and procedures shall be used in:

(1) training pharmacists and pharmacy technicians; and

(2) continuing training related to changes in job responsibilities.

(Indiana Board of Pharmacy; 856 IAC 1-35-6; filed Aug 17, 1995, 8:30 a.m.: 19 IR 41; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-35-7 Identification

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 7. (a) The public shall be able to identify a pharmacist from a pharmacy technician while engaged in the provision of pharmaceutical care.

(b) A pharmacy technician shall:

(1) wear identification clearly stating that the person is a pharmacy technician while on duty; and

(2) identify himself or herself verbally in any telephonic or electronic communication as a pharmacy technician.

(c) No person, other than a person who has met the qualifications established in section 4 of this rule, will be permitted to wear identification using the words “pharmacy technician” or similar wording that may confuse or deceive another person. (Indiana Board of Pharmacy; 856 IAC 1-35-7; filed Aug 17, 1995, 8:30 a.m.: 19 IR 41; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 36. Temporary Variances

856 IAC 1-36-1 Exceptions

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. A person subject to the regulations of the board may request that the board grant a temporary variance from any rule adopted by the board, except rules concerning examinations, experience hours, and requirements for licensure. (Indiana Board of Pharmacy; 856 IAC 1-36-1; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4534; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-2 Submission of a request for temporary variance

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. A request for a temporary variance must be submitted to the board in writing. Each request must contain the following information:

(1) The name, address, and license or permit number of the applicant.

(2) The name of the responsible pharmacist and the specific location at which activities will be conducted under the temporary variance.

(3) The citation to the specific rule from which the applicant seeks a temporary variance.

(4) A detailed explanation of the purpose of the temporary variance.

(5) An assessment of the impact on the public if the variance is granted.

(6) A statement of the conditions which would cause the applicant to apply for renewal of the temporary variance.

(7) The beginning, midpoint, and ending dates of the proposed demonstration project.

(Indiana Board of Pharmacy; 856 IAC 1-36-2; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4534; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-3 Positive impact on delivery of pharmaceutical care
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. Temporary variances shall only be granted for demonstration projects which are expected to have a positive impact on the delivery of pharmaceutical care. Justification for that expectation shall be fully explained. The board shall not grant any temporary variance which threatens public health, safety, or welfare. (Indiana Board of Pharmacy; 856 IAC 1-36-3; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-4 Period of time
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. The board shall grant a temporary variance for a period of no more than six (6) months. Any person who receives a temporary variance shall submit to the board a written report of the effects of the demonstration project at the midpoint and at the conclusion of the temporary variance. (Indiana Board of Pharmacy; 856 IAC 1-36-4; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-5 Renewal
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. A temporary variance may be renewed by the Indiana board of pharmacy (board) for an additional six (6) months. A temporary variance shall not be renewed more than five (5) times. Requests for renewal of a variance shall be submitted in writing to the board not less than thirty (30) days prior to the expiration of the variance and shall contain at least the information required by section 2 of this rule. (Indiana Board of Pharmacy; 856 IAC 1-36-5; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)

856 IAC 1-36-6 Revocation
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. The board may revoke any temporary variance for cause, including, but not limited to, a finding that the temporary variance poses or may pose a threat to public health, safety, or welfare. The person requesting the temporary variance has the obligation to report any such potential threat to the board immediately upon the discovery of such potential threat, or as soon as possible after such discovery. (Indiana Board of Pharmacy; 856 IAC 1-36-6; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-7 Public notice
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 7. The board shall give public notice of requests for temporary variances at not less than two (2) consecutive regular meetings before voting to grant or deny a request for a temporary variance. (Indiana Board of Pharmacy; 856 IAC 1-36-7; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-8 Justification of denial
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 8. The board shall set forth in writing its reasons for granting or denying a temporary variance. (Indiana Board of Pharmacy; 856 IAC 1-36-8; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-9 Copies of requests
Authority: IC 25-26-13-4
Affected: IC 25-26-13-5

Sec. 9. The executive director shall retain copies of all requests for temporary variances and the board's reasons for granting or denying requests as part of the record of it proceedings maintained under IC 25-26-13-5. (Indiana Board of Pharmacy; 856 IAC 1-36-9; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

End of section

ARTICLE 48. CONTROLLED SUBSTANCES

IC 35-48-1
Chapter 1. Definitions

IC 35-48-1-1
(Repealed by P.L.5-1988, SEC.208.)

IC 35-48-1-2
Sec. 2. The definitions in this chapter apply throughout this article.
As added by P.L.5-1988, SEC.182.

IC 35-48-1-3
Sec. 3. "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(1) a practitioner or by his authorized agent; or

(2) the patient or research subject at the direction and in the presence of the practitioner.

As added by P.L.5-1988, SEC.183.

IC 35-48-1-4
Sec. 4. "Advisory committee" refers to the controlled substances advisory committee established under IC 35-48-2-1.
As added by P.L.5-1988, SEC.184.

IC 35-48-1-5
Sec. 5. "Agent" means an authorized person who acts on behalf of, or at the direction of, a manufacturer, distributor, or dispenser, but it does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
As added by P.L.5-1988, SEC.185.

IC 35-48-1-6
Sec. 6. "Board" refers to the Indiana state board of pharmacy.
As added by P.L.5-1988, SEC.186.

IC 35-48-1-7
Sec. 7. "Cocaine" includes coca leaves and any salt, compound, or derivative of coca leaves, and any salt, compound, isomer, derivative, or preparation which is chemically equivalent or identical to any of these substances. However, decocainized coca leaves or extraction of coca leaves that do not contain cocaine or ecgonine are not included.
As added by P.L.5-1988, SEC.187.

IC 35-48-1-8
(*Repealed by P.L.3-1989, SEC.224.)*

IC 35-48-1-9
Sec. 9. "Controlled substance" means a drug, substance, or immediate precursor in schedule I, II, III, IV, or V under:

(1) IC 35-48-2-4, IC 35-48-2-6, IC 35-48-2-8, IC 35-48-2-10, or IC 35-48-2-12, if IC 35-48-2-14 does not apply; or

(2) a rule adopted by the board, if IC 35-48-2-14 applies.

As added by P.L.5-1988, SEC.189.

IC 35-48-1-10
Sec. 10. "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.
As added by P.L.5-1988, SEC.190.

IC 35-48-1-11
Sec. 11. "Delivery" means:

(1) an actual or constructive transfer from one (1) person to another of a controlled substance, whether or not there is an agency relationship; or

(2) the organizing or supervising of an activity described in subdivision (1).

As added by P.L.5-1988, SEC.191. Amended by P.L.165-1990, SEC.1.

IC 35-48-1-12
Sec. 12. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner and includes the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.
As added by P.L.5-1988, SEC.192.

IC 35-48-1-13

YAMD.1988

Sec. 13. "Dispenser" means a practitioner who dispenses.
As added by P.L.5-1988, SEC.193.

IC 35-48-1-14
Sec. 14. "Distribute" means to deliver other than by administering or dispensing a controlled substance.
As added by P.L.5-1988, SEC.194.

IC 35-48-1-15
Sec. 15. "Distributor" means a person who distributes.
As added by P.L.5-1988, SEC.195.

IC 35-48-1-16
Sec. 16. "Drug" has the meaning set forth in IC 16-42-19-2. It does not include devices or their components, parts, or accessories, nor does it include food.

As added by P.L.5-1988, SEC.196. Amended by P.L.2-1993, SEC.190.

IC 35-48-1-17
Sec. 17. "Immediate precursor" means a substance which the board has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediate used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.
As added by P.L.5-1988, SEC.197.

IC 35-48-1-18
Sec. 18. "Manufacture" means:

(1) the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. It does not include the preparation, compounding, packaging, or labeling of a controlled substance:

(A) by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(B) by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale; or

(2) the organizing or supervising of an activity described in subdivision (1).

As added by P.L.5-1988, SEC.198. Amended by P.L.165-1990, SEC.2; P.L.17-2001, SEC.18.

IC 35-48-1-19
Sec. 19. "Marijuana" means any part of the plant genus Cannabis

whether growing or not; the seeds thereof; the resin extracted from any part of the plant, including hashish and hash oil; any compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant; fiber produced from the stalks; oil or cake made from the seeds of the plant; any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom); or the sterilized seed of the plant which is incapable of germination.
As added by P.L.5-1988, SEC.199.

IC 35-48-1-20

Sec. 20. "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical to any of the substances referred to in subdivision (1) of this definition, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

As added by P.L.5-1988, SEC.200.

IC 35-48-1-21

Sec. 21. "Opiate" means a substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under IC 35-48-2, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.
As added by P.L.5-1988, SEC.201.

IC 35-48-1-22

Sec. 22. "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.
As added by P.L.5-1988, SEC.202.

IC 35-48-1-23

Sec. 23. "Poppy straw" means any part, except the seeds, of the opium poppy, after mowing.
As added by P.L.5-1988, SEC.203.

IC 35-48-1-24

Sec. 24. "Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Indiana.
As added by P.L.5-1988, SEC.204.

IC 35-48-1-25

Sec. 25. "Prescription drug" means a controlled substance or a legend drug (as defined in IC 16-18-2-199).
As added by P.L.5-1988, SEC.205. Amended by P.L.2-1993, SEC.191.

IC 35-48-1-26

Sec. 26. "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.
As added by P.L.5-1988, SEC.206.

IC 35-48-1-27

Sec. 27. "Ultimate user" means a person who lawfully possesses a controlled substance for the person's own use, for the use of a member of the person's household, or for administering to an animal owned by the person or by a member of the person's household.
As added by P.L.5-1988, SEC.207.

IC 35-48-2

Chapter 2. Classification of Drugs

IC 35-48-2-1

Sec. 1. (a) The board shall administer this article and may recommend to the general assembly the addition, deletion, or rescheduling of all substances listed in the schedules in sections 4, 6, 8, 10, and 12 of this chapter by submitting a report of such recommendations to the legislative council. In making a determination regarding a substance, the board shall consider the following:

(1) The actual or relative potential for abuse.

(2) The scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the substance.

(4) The history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) The risk to public health.

(7) The potential of the substance to produce psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this article.

(b) After considering the factors enumerated in subsection (a), the board shall make findings and recommendations concerning the control of the substance if it finds the substance has a potential for abuse.

(c) If the board finds that a substance is an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated or rescheduled to a more restrictive schedule as a controlled substance under federal law and notice is given to the board, the board shall recommend similar control of the substance under this article in the board's report to the general assembly, unless the board objects to inclusion or rescheduling. In that case, the board shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall publish its findings.

(e) If a substance is rescheduled to a less restrictive schedule or deleted as a controlled substance under federal law, the substance is rescheduled or deleted under this article. If the board objects to inclusion, rescheduling, or deletion of the substance, the board shall notify the chairman of the legislative council not more than thirty (30) days after the federal law is changed and the substance may not be rescheduled or deleted until the conclusion of the next complete session of the general assembly. The notice from the board to the chairman of the legislative council must be published.

(f) There is established a fifteen (15) member controlled substances advisory committee to serve as a consultative and advising body to the board in all matters relating to the classification, reclassification, addition to, or deletion from of all substances classified as controlled substances in schedules I to IV or substances not controlled or yet to come into being. In addition, the advisory committee shall conduct hearings and make recommendations to the board regarding revocations, suspensions, and restrictions of registrations as provided in IC 35-48-3-4. All hearings shall be conducted in accordance with IC 4-21.5-3. The advisory committee shall be made up of:

(1) two (2) physicians licensed under IC 25-22.5, one (1) to be elected by the medical licensing board of Indiana from among its members and one (1) to be appointed by the governor;

(2) two (2) pharmacists, one (1) to be elected by the state board of pharmacy from among its members and one (1) to be appointed by the governor;

(3) two (2) dentists, one (1) to be elected by the state board of dentistry from among its members and one (1) to be appointed by the governor;

(4) the state toxicologist or the designee of the state toxicologist;

(5) two (2) veterinarians, one (1) to be elected by the state board

of veterinary medical examiners from among its members and one (1) to be appointed by the governor;

(6) one (1) podiatrist to be elected by the board of podiatric medicine from among its members;

(7) one (1) advanced practice nurse with authority to prescribe legend drugs as provided by IC 25-23-1-19.5 who is:

(A) elected by the state board of nursing from among the board's members; or

(B) if a board member does not meet the requirements under IC 25-23-1-19.5 at the time of the vacancy on the advisory committee, appointed by the governor;

(8) the superintendent of the state police department or the superintendent's designee; and

(9) three (3) members appointed by the governor who have demonstrated expertise concerning controlled substances.

(g) All members of the advisory committee elected by a board shall serve a term of one (1) year and all members of the advisory committee appointed by the governor shall serve a term of four (4) years. Any elected or appointed member of the advisory committee, may be removed for cause by the authority electing or appointing the member. If a vacancy occurs on the advisory committee, the authority electing or appointing the vacating member shall elect or appoint a successor to serve the unexpired term of the vacating member. The board shall acquire the recommendations of the advisory committee pursuant to administration over the controlled substances to be or not to be included in schedules I to V, especially in the implementation of scheduled substances changes as provided in subsection (d).

(h) Authority to control under this section does not extend to distilled spirits, wine, or malt beverages, as those terms are defined or used in IC 7.1, or to tobacco.

(i) The board shall exclude any nonnarcotic substance from a schedule if that substance may, under the Federal Food, Drug, and Cosmetic Act or state law, be sold over the counter without a prescription.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.344, SEC.1; P.L.137-1985, SEC.17; P.L.200-1987, SEC.4; P.L.188-1989, SEC.4; P.L.33-1993, SEC.73; P.L.163-1994, SEC.2; P.L.177-1997, SEC.8; P.L.14-2000, SEC.77.

IC 35-48-2-1.1

(*Repealed by P.L.2-1995, SEC.140.)*

IC 35-48-2-1.5

Sec. 1.5. (a) The advisory committee shall annually elect a chairperson and any other officers that the advisory committee determines necessary from among its members.

(b) Meetings of the advisory committee may be called by:

(1) the advisory committee chairperson; or

(2) a majority of the members of the advisory committee.

(c) Seven (7) members of the committee constitute a quorum.

(d) Notwithstanding IC 1-1-4-1, if at least a quorum of its members are present at a meeting, the committee may take an action by an affirmative vote of at least a majority of the members present and voting.

(e) The advisory committee shall adopt rules under IC 4-22-2 to:

(1) set standards related to the registration and control of the manufacture, distribution, and dispensing of controlled substances, including recordkeeping requirements;

(2) set fees described in IC 25-1-8; and

(3) carry out its responsibilities under IC 35-48-2 through IC 35-48-3 and IC 35-48-6.

(f) The health professions bureau shall provide staff and facilities to the advisory committee under IC 25-1-5.

(g) Each member of the committee who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). Such a member is also entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the department of administration and approved by the state budget agency.

(h) Each member of the committee who is a state employee is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the department of administration and approved by the budget agency.

As added by P.L.200-1987, SEC.5.

IC 35-48-2-2

Sec. 2. Nomenclature. The controlled substances listed in the schedules in sections 4, 6, 8, 10 and 12 of this chapter are included by whatever official, common, usual, chemical, or trade name designated. The number placed in brackets after each substance is its federal Drug Enforcement Administration Controlled Substances Code Number which is to be used for identification purposes on certain certificates of registration.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.2.

IC 35-48-2-3

Sec. 3. (a) The board shall recommend placement of a substance in schedule I under this chapter if it finds that the substance:

(1) has high potential for abuse; and

(2) has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

(b) The board may recommend placement of a substance in schedule I under this chapter if it finds that the substance is classified as a controlled substance in schedule I under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.6.

IC 35-48-2-4

Sec. 4. (a) The controlled substances listed in this section are included in schedule I.

(b) Opiates. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted by rule of the board or unless listed in another schedule, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

Acetylmethadol (9601)
Allylprodine (9602)
Alphacetylmethadol (9603)
Alphameprodine (9604)
Alphamethadol (9605)
Alphamethylfentanyl (9614)
Benzethidine (9606)
Betacetylmethadol (9607)
Betameprodine (9608)
Betamethadol (9609)
Betaprodine (9611)
Clonitazene (9612)
Dextromoramide (9613)
Diampromide (9615)
Diethylthiambutene (9616)
Difenoxin (9168)
Dimenoxadol (9617)
Dimepheptanol (9618)
Dimethylthiambutene (9619)
Dioxaphetyl butyrate (9621)
Dipipanone (9622)
Ethylmethylthiambutene (9623)
Etonitazene (9624)
Etoxeridine (9625)
Furethidine (9626)

Hydroxypethidine (9627)
Ketobemidone (9628)
Levomoramide (9629)

Levophenacylmorphan (9631)
3-Methylfentanyl [N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenyl-propanimide](9813)
MPPP (1-methyl-4-phenyl-4-propionoxypiperidine) (9961)
Morpheridine (9632)
Noracymethadol (9633)
Norlevorphanol (9634)
Normethadone (9635)
Norpipanone (9636)
Phenadoxone (9637)
Phenampromide (9638)
Phenomorphan (9647)
Phenoperidine (9641)
PEPAP [1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine] (9663)
Piritramide (9642)
Proheptazine (9643)
Properidine (9644)
Propiram (9649)
Racemoramide (9645)
Tilidine (9750)
Trimeperidine (9646)

(c) Opium derivatives. Any of the following opium derivatives, their salts, isomers, and salts of isomers, unless specifically excepted by rule of the board or unless listed in another schedule, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

Acetorphine (9319)
Acetyldihydrocodeine (9051)
Benzylmorphine (9052)
Codeine methylbromide (9070)
Codeine-N-Oxide (9053)
Cyprenorphine (9054)
Desomorphine (9055)
Dihydromorphine (9145)
Drotebanol (9335)
Etorphine (except hydrochloride salt) (9056)
Heroin (9200)
Hydromorphinol (9301)
Methyldesorphine (9302)
Methyldihydromorphine (9304)
Morphine methylbromide (9305)
Morphine methylsulfonate (9306)
Morphine-N-Oxide (9307)
Myrophine (9308)
Nicocodeine (9309)
Nicomorphine (9312)
Normorphine (9313)
Pholcodine (9314)
Thebacon (9315)

(d) Hallucinogenic substances. Any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic, psychedelic, or psychogenic substances, their salts, isomers, and salts of isomers, unless specifically excepted by rule of the board or unless listed in another schedule, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 4-Bromo-2, 5-Dimethoxyamphetamine (7391). Some trade or other names: 4-Bromo-2, 5-Dimethoxy-a-methylphenethylamine; 4-Bromo-2, 5-DMA.

(2) 2, 5-Dimethoxyamphetamine (7396). Some trade or other names: 2, 5-Dimethoxy-a-methylphenethylamine; 2, 5-DMA.

(3) 4-Methoxyamphetamine (7411). Some trade or other names: 4-Methoxy-a-methylphenethylamine; Paramethoxyamphetamine; PMA.

(4) 5-methoxy-3, 4-methylenedioxy amphetamine (7401). Other Name: MMDA.

(5) 4-methyl-2, 5-dimethoxyamphetamine (7395). Some trade and other names: 4-methyl-2, 5-dimethoxy-a-methylphenethylamine; DOM; and STP.

(6) 3, 4-methylenedioxy amphetamine (7400). Other name: MDA.

(7) 3, 4-methylenedioxymethamphetamine (MDMA) (7405).

(8) 3, 4, 5-trimethoxy amphetamine (7390). Other name: TMA.

(9) Bufotenine (7433). Some trade and other names: 3-(B-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminonethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine.

(10) Dimethyltryptamine (7434). Some trade or other names: N, N-Diethyltryptamine; DET.

(11) Diethyltryptamine (7435). Some trade or other names: DMT.

(12) Ibogaine (7260). Some trade and other names: 7-Ethyl-6, 6b, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1', 2': 1, 2, azepino 4, 5-b) indole; tabernanthe iboga.

(13) Lysergic acid diethylamide (7315). Other name: LSD.

(14) Marijuana (7360).

(15) Mescaline (7381).

(16) Parahexyl (7374). Some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-Tetrahydro-6, 6, 9-trimethyl-6H-dibenzo (b,d) pyran; Snyhexyl.

(17) Peyote (7415), including:

(A) all parts of the plant that are classified botanically as lophophora williamsii lemaire, whether growing or not;

(B) the seeds thereof;

(C) any extract from any part of the plant; and

(D) every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

(18) N-ethyl-3-piperidyl benzilate (7482). Other name: DMZ.

(19) N-methyl-3-piperidyl benzilate (7484). Other name: LBJ.

(20) Psilocybin (7437).

(21) Psilocyn (7438).

(22) Tetrahydrocannabinols (7370), including synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and synthetic substances,

derivatives, and their isomers with similar chemical structure and pharmacological activity such as:

(A) Δ^1 cis or trans tetrahydrocannabinol, and their optical isomers;

(B) Δ^6 cis or trans tetrahydrocannabinol, and their optical isomers; and

(C) $\Delta^{3,4}$ cis or trans tetrahydrocannabinol, and their optical isomers.

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered. Other name: THC.

(23) Ethylamine analog of phencyclidine (7455). Some trade or other names: N-Ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE.

(24) Pyrrolidine analog of phencyclidine (7458). Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCP_y; PHP.

(25) Thiophene analog of phencyclidine (7470). Some trade or other names: 1-(1-(2-thienyl) cyclohexyl) piperidine; 2-Thienyl Analog of Phencyclidine; TPCP.

(e) Depressants. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Gamma-hydroxybutyric acid (other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate) (2010)

Mecloqualone (2572)

Methaqualone (2565)

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Fenethylline (1503)

N-ethylamphetamine (1475)

Methcathinone (1237) (Some other trade names: 2-Methylamino-1-Phenylpropan-l-one; Ephedrone; Monomethylpropion; UR 1431.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.3; Acts 1981, P.L.170, SEC.2; P.L.333-1983, SEC.1; P.L.327-1985, SEC.1; P.L.156-1986, SEC.4; P.L.200-1987, SEC.7; P.L.163-1994, SEC.3; P.L.2-1996, SEC.286; P.L.288-2001, SEC.15.

IC 35-48-2-5

IC 35-48-2-5 Sec. 5. (a) The board shall recommend placement of a substance in schedule II under this chapter if it finds that:

(1) the substance has high potential for abuse;

(2) the substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and

(3) the abuse of the substance may lead to sev ere psychological or physical dependence.

(b) The board may recommend placement of a substance in schedule II under this chapter if it finds that the substance is classified as a controlled substance in schedule II under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.8.

IC 35-48-2-6

Sec. 6. (a) The controlled substances listed in this section are included in schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, naloxone, naltrexone, and their respective salts but including:

(A) raw opium (9600);

(B) opium extracts (9610);

(C) opium fluid ex tracts (9620);

(D) powdered opium (9639);

(E) granulated opium (9640);

(F) tincture of opium (9630);

(G) codeine (9050);

(H) ethylmorphine (9190);

(I) etorphine hydrochloride (9059);

(J) hydrocodone (9193);

(K) hydromorphone (9150);

(L) metopon (9260);

(M) morphine (9300);

(N) oxycodone (9143);

(O) oxymorphone (9652); and

(P) thebaine (9333).

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (b)(1) of this section, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Cocaine (9041).

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy) (9670).

(c) Opiates. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

Alfentanil (9737)

Alphaprodine (9010)

Anileridine (9020)

Bezitramide (9800)

Bulk dextropropoxyphene (nondosage forms) (9273)

Dihydrocodeine (9120)

Diphenoxylate (9170)

Fentanyl (9801)

Isomethadone (9226)

Levomethorphan (9210)

Levorphanol (9220)

Metazocine (9240)

Methadone (9250)

Methadone-Intermediate, 4-cyano-2-dimethyl-amino-4, 4-diphenyl butane (9254)

Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane- carboxylic acid (9802)

Pethidine (Meperidine) (9230)

Pethidine-Intermediate- A, 4-cyano-1-methyl-4-phenylpiperidine (9232)

Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate (9233)

Pethidine-Intermediate-C,1-methyl-4-phenylpiperidine-4-carbo xylic acid (9234)

Phenazodine (9715)

Piminodine (9730)

Racemethorphan (9732)

Racemorphan (9733)

Sufentanil (9740)

(d) Stimulants. Any material compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers (1100).

(2) Methamphetamine, including its salts, isomers, and salts of its isomers (1105).

(3) Phenmetrazine and its salts (1631).

(4) Methylphenidate (1724).

(e) Depressants. Unless specifically excepted by rule of the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Amobarbital (2125)

Gamma hydroxybutyrate

Pentobarbital (2270)

Phencyclidine (7471)

Secobarbital (2315)

(f) Immediate precursors. Unless specifically excepted by rule of the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine: Phenylacetone (8501). Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine (7460); or

(B) 1-piperidinocyclohexanecarbonitrile (PCC) (8603).

(g) Hallucinogenic substances:

Dronabinol (synthetic) in sesame oil and encapsulated in a soft

gelatin capsule in a United States Food and Drug Administration approved drug product (7369).
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.4; Acts 1981, P.L.170, SEC.3; P.L.333-1983, SEC.2; P.L.77-1984, SEC.13; P.L.327-1985, SEC.2; P.L.156-1986, SEC.5; P.L.329-1987, SEC.1; P.L.31-1998, SEC.9.

IC 35-48-2-7

Sec. 7. (a) The board shall recommend placement of a substance in schedule III under this chapter if it finds that:

(1) the substance has a potential for abuse less than the substances listed in schedule I and II under this chapter;

(2) the substance has currently accepted medical use in treatment in the United States; and

(3) abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

(b) The board may recommend placement of a substance in schedule III under this chapter if it finds that the substance is classified as a controlled substance in schedule III under federal law.
As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.9.

IC 35-48-2-8

Sec. 8. (a) The controlled substances listed in this section are included in schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on April 1, 1986, as excepted compounds under 21 CFR 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or that is the same except that it contains a lesser quantity of controlled substances (1405).

(2) Benzphetamine (1228).

(3) Chlorphentermine (1645).

(4) Clortermine (1647).

(5) Phendimetrazine (1615).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing:

(A) amobarbital (2125);

(B) secobarbital (2315);

(C) pentobarbital (2270); or

(D) any of their salts;

and one (1) or more other active medicinal ingredients which are not listed in any schedule.

(2) Any suppository dosage form containing:

(A) amobarbital (2125);

(B) secobarbital (2315);

(C) pentobarbital (2270); or

(D) any of their salts;

and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt thereof (2100).

(4) Chlorhexadol (2510).

(5) Glutethimide (2550).

(6) Lysergic acid (7300).

(7) Lysergic acid amide (7310).

(8) Methyprylon (2575).

(9) Sulfondiethylmethane (2600).

(10) Sulfonethylmethane (2605).

(11) Sulfonmethane (2610).

(12) A combination product containing tiletimine and zolazepam (Telazol) (7295).

(13) Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. (2012).

(d) Nalorphine (a narcotic drug) (9400).

(e) Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in the following limited quantities:

(1) Not more than 1.8 grams of codeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium (9803).

(2) Not more than 1.8 grams of codeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9804).

(3) Not more than 300 milligrams of dihydrocodeinone, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium (9805).

(4) Not more than 300 milligrams of dihydrocodeinone, per 100 milliliters or not more than 15 milligrams per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts (9806).

(5) Not more than 1.8 grams of dihydrocodeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9807).

(6) Not more than 300 milligrams of ethylmorphine, per 100 milliliters or not more than 15 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9808).

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9809).

(8) Not more than 50 milligrams of morphine, per 100 milliliters or per 100 grams with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts (9810).

(f) Anabolic steroid (as defined in 21 U.S.C. 802(41)(A) and 21 U.S.C. 802(41)(B)).

(g) The board shall except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections (b) through (e) from the application of any part of this article if the compound, mixture, or preparation contains one (1) or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

(h) Any material, compound, mixture, or preparation which contains any quantity of Ketamine.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.2, SEC.86; Acts 1979, P.L.303, SEC.5; Acts 1981, P.L.170, SEC.4; P.L.333-1983, SEC.3; P.L.200-1987, SEC.10; P.L.48-1991, SEC.76; P.L.1-1994, SEC.171; P.L.31-1998, SEC.10; P.L.288-2001, SEC.16.

IC 35-48-2-9

Sec. 9. (a) The board shall recommend placement of a substance in schedule IV under this chapter if it finds that:

(1) the substance has a low potential for abuse relative to substances in schedule III under this chapter;

(2) the substance has currently accepted medical use in treatment in the United States; and

(3) abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in schedule III under this chapter.

(b) The board may recommend placement of a substance in schedule IV under this chapter if it finds that the substance is classified as a controlled substance in schedule IV under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.11.

IC 35-48-2-10

Sec. 10. (a) The controlled substances listed in this section are included in schedule IV.

(b) Narcotic drugs. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in the following limited quantities:

(1) Not more than 1 milligram of difenoxin (9618) and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha- (+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane (9273).

(c) Depressants. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Alprazolam (2882).
Barbital (2145).
Bromazepam (2748).
Camazepam (2749).
Chloral betaine (2460).
Chloral hydrate (2465).
Chlordiazepoxide (2744).
Clobazam (2751).
Clonazepam (2737).
Clorazepate (2768).
Clotiazepam (2752).
Cloxazolam (2753).
Delorazepam (2754).
Diazepam (2765).
Estazolam (2756).
Ethchlorvynol (2540).
Ethinamate (2545).
Ethyl loflazepate (2758).
Fludiazepam (2759).
Flunitrazepam (2763).
Flurazepam (2767).
Halazepam (2762).
Haloxazolam (2771).
Ketazolam (2772).
Loprazolam (2773).
Lorazepam (2885).
Lormetazepam (2774).
Mebutamate (2800).
Medazepam (2836).
Meprobamate (2820).
Methohexital (2264).
Methylphenobarbital (mephobarbital) (2250).
Midazolam (2884).
Nimetazepam (2837).
Nitrazepam (2834).
Nordiazepam (2838).
Oxazepam (2835).
Oxazolam (2839).
Paraldehyde (2585).
Petrichloral (2591).
Phenobarbital (2285).
Pinazepam (2883).
Prazepam (2764).
Quazepam (2881).
Temazepam (2925).
Tetrazepam (2886).
Triazolam (2887).
Zolpidem (Ambien) (2783).

(d) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible.

Fenfluramine (1670).

(e) Stimulants. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion (1608).
(2) Mazindol (1605).
(3) Phentermine (1640).
(4) Pemoline (including organometallic complexes and chelates thereof) (1530).
(5) Pipradrol (1750).
(6) SPA ((-)-1-dimethylamino-1,2-diphenylethane (1635).

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances including its salts:

(1) Pentazocine (9709).

(g) The board may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection (b), (c), (d), (e), or (f) from the application of any part of this article if the compound, mixture, or preparation contains one (1) or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.344, SEC.2; Acts 1979, P.L.303, SEC.6; Acts 1981, P.L.170, SEC.5; P.L.333-1983, SEC.4; P.L.77-1984, SEC.14; P.L.200-1987, SEC.12; P.L.288-2001, SEC.17.

IC 35-48-2-11

Sec. 11. (a) The board shall recommend placement of a substance in schedule V under this chapter if it finds that:

(1) the substance has low potential for abuse relative to the controlled substances listed in schedule IV under this chapter;

(2) the substance has currently accepted medical use in treatment in the United States; and

(3) the substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in schedule IV under this chapter.

(b) The board may recommend placement of a substance in schedule V under this chapter if it finds that the substance is classified as a controlled substance in schedule V under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.13.

IC 35-48-2-12

Sec. 12. (a) The controlled substances listed in this section are included in schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in the following quantities, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(6) Not more than 0.5 milligrams of difenoxin (9168), and not less than 25 micrograms of atropine sulfate per dosage unit.

(c) Buprenorphine (9064).

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.7; Acts 1981, P.L.170, SEC.6; P.L.327-1985, SEC.3.

IC 35-48-2-13

(*Repealed by Acts 1979, P.L.303, SEC.13.)*

IC 35-48-2-14

Sec. 14. (a) The board may adopt rules under IC 4-22-2 to reclassify a controlled substance:

(1) from a more restrictive schedule to a less restrictive schedule; or

(2) as a substance that is not a controlled substance;

if the board finds that the substance qualifies for reclassification under this chapter and that the same reclassification has been made in a controlled substance schedule under federal law.

(b) If the board reclassifies a controlled substance under subsection (a), the board shall recommend the same reclassification to the general assembly under section 1 of this chapter.

(c) Notwithstanding a provision in this chapter that classifies a controlled substance in a more restrictive schedule than a rule adopted under subsection (a), a person who manufactures, distributes, dispenses, possesses, or uses a controlled substance in compliance with the requirements applicable to the less restrictive schedule to which a controlled substance is reclassified under subsection (a) does not commit an offense under this article.

(d) Notwithstanding a provision in this chapter that classifies a substance as a controlled substance, a person does not commit an offense under this article if the board has reclassified the controlled substance as a substance that is not a controlled substance.

As added by P.L.200-1987, SEC.14.

IC 35-48-3

Chapter 3. Registration and Control

IC 35-48-3-1

Sec. 1. Rules. The board may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within this state.

As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-2

Sec. 2. (a) Any humane society, animal control agency, or governmental entity operating an animal shelter or other animal impounding facility is entitled to receive a limited permit only for the purpose of buying, possessing, and using:

(1) sodium pentobarbital to euthanize injured, sick, homeless, or unwanted domestic pets and animals;

(2) ketamine and ketamine products to anesthetize or immobilize fractious domestic pets and animals; and

(3) a combination product containing tiletimine and zolazepam as an agent for the remote chemical capture of domestic pets or animals that otherwise cannot be restrained or captured.

(b) A humane society, animal control agency, or governmental entity entitled to receive a permit under this chapter must:

(1) apply to the board according to the rules established by the board;

(2) pay annually to the board a fee set by the board for the limited permit; and

(3) submit proof, as determined by the board, that the employees of an applicant who will handle a controlled substance are sufficiently trained to use and administer the controlled substance.

(c) All fees collected by the board under this section shall be credited to the state board of pharmacy account.

(d) Storage, handling, and use of controlled substances obtained according to this section are subject to the rules adopted by the board.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.193-1987, SEC.16; P.L.136-2001, SEC.1.

IC 35-48-3-3

Sec. 3. (a) Every person who manufactures or distributes any controlled substance within this state or who proposes to engage in the manufacture or distribution of any controlled substance within this state, must obtain biennially a registration issued by the board in accordance with its rules.

(b) Every person who dispenses or proposes to dispense any controlled substance within Indiana must have a registration issued by the board in accordance with its rules. A registration issued to a dispenser under this subsection expires whenever the dispenser's license as a practitioner expires. The board shall renew a dispenser's registration under this subsection concurrently with any state license authorizing the dispenser to act as a practitioner.

(c) Persons registered by the board under this article to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this chapter.

(d) The following persons need not register and may lawfully possess controlled substances under this article:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if he is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.

(3) An ultimate user or a person in possession of any controlled substance under a lawful order of a practitioner or in lawful possession of a schedule V substance.

(e) The board may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

(f) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, dispenses, or possesses controlled substances.

(g) The board may inspect the establishment of a registrant or applicant for registration in accordance with the board's rules.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.156-1986, SEC.6.

IC 35-48-3-4

Sec. 4. Registration. (a) The board shall register an applicant to

manufacture or distribute controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board shall consider:

(1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable state and local law;

(3) any convictions of the applicant under any federal and state laws relating to any controlled substance;

(4) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

(5) furnishing by the applicant of false or fraudulent material in any application filed under this article;

(6) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

(7) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) of this section does not entitle a registrant to manufacture and distribute controlled substances in

schedules I or II other than those specified in the registration.

(c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in schedules II through V if they are authorized to dispense or conduct research under the law of this state. The board need not require separate registration under this chapter for practitioners engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already registered under this chapter in another capacity, to the extent authorized by his registration in that other capacity.

(d) Registration to conduct research or instructional activities with controlled substances in schedules I through V does not entitle a registrant to conduct research or instructional activities with controlled substances other than those approved by the controlled substances advisory committee in accordance with the registration.

Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding fees) entitles them to be registered under this article.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1981, P.L.170, SEC.7.

IC 35-48-3-5

Sec. 5. Denial, Revocation, and Suspension of Registration. (a) An application for registration or re-registration submitted pursuant to and a registration issued under section 3 of this chapter to manufacture, distribute, or dispense a controlled substance may be denied, suspended or revoked by the board upon a finding by the advisory committee that the applicant or registrant:

(1) has furnished false or fraudulent material information in any application filed under this article;

(2) has violated any state or federal law relating to any controlled substance;

(3) has had his federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances; or

(4) has failed to maintain reasonable controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

(b) The board may limit revocation or suspension of a registration or the denial of an application for registration or re-registration to the particular controlled substance with respect to which grounds for revocation, suspension or denial exist.

(c) If the board suspends or revokes a registration or denies an application for re-registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation or denial order may be placed under seal. The board may require the removal of such substances from the premises. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation or denial order becoming final, all controlled substances may be forfeited to the state.

(d) The board shall promptly notify the drug enforcement administration of all orders suspending or revoking registration, all orders denying any application for registration or re-registration, and all forfeitures of controlled substances.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1981, P.L.170, SEC.8.

IC 35-48-3-6

Sec. 6. (a) Before recommending a denial, suspension, or revocation of a registration, or before refusing a renewal of registration, the advisory committee shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be denied. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the advisory committee at a time and place not less than thirty (30) days after the date of service of the order, but in the case of a denial or renewal of registration the show cause order shall be served not later than thirty (30) days before the expiration of the registration. These proceedings shall be conducted in accordance with IC 4-21.5 without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

(b) The advisory committee may recommend suspension, and the board may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under section 4 of this chapter, or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the board or dissolved by a court of competent jurisdiction.

(c) If an applicant for re-registration (who is doing business under a registration previously granted and not revoked nor suspended) has applied for re-registration at least forty-five (45) days before the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the board so issues its order. The board may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for re-registration at least forty-five (45) days before expiration of the existing registration, with or without request by the registrant, if the board finds that such extension is not inconsistent with the public health and safety.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.7-1987, SEC.166.

IC 35-48-3-7

Sec. 7. Records of Registrants. Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the board issues.

As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-8

Sec. 8. Order Forms. Controlled substances in schedules I and II

shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms is deemed compliance with this section.
As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-9

Sec. 9. (a) Except for dosages medically required for a period of not more than forty-eight (48) hours that are dispensed by or on the direction of a practitioner, or medication dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

(b) In emergency situations, as defined by rule of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of section 7 of this chapter. No prescription for a schedule II substance may be refilled.

(c) Except for dosages medically required for a period of not more than forty-eight (48) hours that are dispensed by or on the direction of a practitioner, or medication dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under IC 16-42-19, shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date thereof or be refilled more than five (5) times, unless renewed by the practitioner.

(d) A controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.
As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.2-1993, SEC.192; P.L.163-1994, SEC.4.

IC 35-48-3-10

(*Repealed by P.L.157-1999, SEC.2.)*

IC 35-48-3-11

Sec. 11. (a) Only a physician licensed under IC 25-22.5 may treat a patient with a Schedule III or Schedule IV controlled substance for the purpose of weight reduction or to control obesity.

(b) A physician licensed under IC 25-22.5 may not prescribe, dispense, administer, supply, sell, or give any amphetamine, sympathomimetic amine drug, or compound designated as a Schedule III or Schedule IV controlled substance under IC 35-48-2-8 and IC 35-48-2-10 for a patient for purposes of weight reduction or to control obesity, unless the physician does the following:

(1) Determines:

(A) through review of:

(i) the physician's records of prior treatment of the patient; or

(ii) the records of prior treatment of the patient provided by a previous treating physician or weight loss program;

that the physician's patient has made a reasonable effort to lose weight in a treatment program using a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise without using controlled substances; and

(B) that the treatment described in clause (A) has been ineffective for the physician's patient.

(2) Obtains a thorough history and performs a thorough physical examination of the physician's patient before initiating a treatment plan using a Schedule III or Schedule IV controlled substance for purposes of weight reduction or to control obesity.

(c) A physician licensed under IC 25-22.5 may not begin and shall discontinue using a Schedule III or Schedule IV controlled substance for purposes of weight reduction or to control obesity after the physician determines in the physician's professional judgment that:

(1) the physician's patient has failed to lose weight using a treatment plan involving the controlled substance;

(2) the controlled substance has provided a decreasing contribution toward further weight loss for the patient unless continuing to take the controlled substance is medically necessary or appropriate for maintenance therapy;

(3) the physician's patient:

(A) has a history of; or

(B) shows a propensity for;

alcohol or drug abuse; or

(4) the physician's patient has consumed or disposed of a controlled substance in a manner that does not strictly comply with a treating physician's direction.
As added by P.L.157-1999, SEC.1. Amended by P.L.37-2001, SEC.1.

IC 35-48-4

Chapter 4. Offenses Relating to Controlled Substances

IC 35-48-4-1

Sec. 1. (a) A person who:

(1) knowingly or intentionally:

(A) manufactures;

(B) finances the manufacture of;

(C) delivers; or

(D) finances the delivery of;

cocaine, a narcotic drug, or methamphetamine, pure or adulterated, classified in schedule I or II; or

(2) possesses, with intent to:

(A) manufacture;

(B) finance the manufacture of;

(C) deliver; or

(D) finance the delivery of;

cocaine, a narcotic drug, or methamphetamine, pure or adulterated, classified in schedule I or II;

commits dealing in cocaine, a narcotic drug, or methamphetamine, a Class B felony, except as provided in subsection (b).

(b) The offense is a Class A felony if:

(1) the amount of the drug involved weighs three (3) grams or more;

(2) the person:

(A) delivered; or

(B) financed the delivery of;

the drug to a person under eighteen (18) years of age at least three (3) years junior to the person; or

(3) the person manufactured, delivered or financed the delivery of the drug:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.96; Acts 1979, P.L.303, SEC.8; P.L.296-1987, SEC.5; P.L.165-1990, SEC.3; P.L.296-1995, SEC.3; P.L.65-1996, SEC.11; P.L.17-2001, SEC.19.

IC 35-48-4-2

Sec. 2. (a) A person who:

(1) knowingly or intentionally:

(A) manufactures;

(B) finances the manufacture of;

(C) delivers; or

(D) finances the delivery of;

a controlled substance, pure or adulterated, classified in schedule I, II, or III, except marijuana, hash oil, or hashish; or

(2) possesses, with intent to:

(A) manufacture;

(B) finance the manufacture of;

(C) deliver; or

(D) finance the delivery of;

a controlled substance, pure or adulterated, classified in schedule I, II, or III, except marijuana, hash oil, or hashish;
commits dealing in a schedule I, II, or III controlled substance, a Class B felony, except as provided in subsection (b).

(b) The offense is a Class A felony if:

(1) the person:

(A) delivered; or

(B) financed the delivery of;

the substance to a person under eighteen (18) years of age at least three (3) years junior to the person; or

(2) the person delivered or financed the delivery of the substance:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.97; Acts 1979, P.L.303, SEC.9; P.L.296-1987, SEC.6; P.L.165-1990, SEC.4; P.L.296-1995, SEC.4; P.L.65-1996, SEC.12; P.L.17-2001, SEC.20.

IC 35-48-4-3

Sec. 3. (a) A person who:

(1) knowingly or intentionally:

(A) manufactures;

(B) finances the manufacture of;

(C) delivers; or

(D) finances the delivery of;

a controlled substance, pure or adulterated, classified in schedule IV; or

(2) possesses, with intent to manufacture or deliver, a controlled substance, pure or adulterated, classified in schedule IV;
commits dealing in a schedule IV controlled substance, a Class C felony, except as provided in subsection (b).

(b) The offense is a Class B felony if:

(1) the person:

(A) delivered; or

(B) financed the delivery of;

the substance to a person under eighteen (18) years of age at least three (3) years junior to the person; or

(2) the person delivered or financed the delivery of the substance:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.98; P.L.296-1987, SEC.7; P.L.165-1990, SEC.5; P.L.296-1995, SEC.5; P.L.65-1996, SEC.13; P.L.17-2001, SEC.21.

IC 35-48-4-4

Sec. 4. (a) A person who:

(1) knowingly or intentionally:

(A) manufactures;

(B) finances the manufacture of;

(C) delivers; or

(D) finances the delivery of;

a controlled substance, pure or adulterated, classified in schedule V; or

(2) possesses, with intent to:

(A) manufacture;

(B) finance the manufacture of;

(C) deliver; or

(D) finance the delivery of;

a controlled substance, pure or adulterated, classified in schedule V;
commits dealing in a schedule V controlled substance, a Class D felony, except as provided in subsection (b).

(b) The offense is a Class B felony if:

(1) the person:

(A) delivered; or

(B) financed the delivery of;

the substance to a person under eighteen (18) years of age at least three (3) years junior to the person; or

(2) the person delivered or financed the delivery of the substance:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.99; P.L.296-1987, SEC.8; P.L.165-1990, SEC.6; P.L.296-1995, SEC.6; P.L.65-1996, SEC.14; P.L.17-2001, SEC.22.

IC 35-48-4-4.5

Sec. 4.5. (a) A person who knowingly or intentionally delivers or finances the delivery of any substance, other than a controlled substance or a drug for which a prescription is required under federal or state law, that:

(1) is expressly or impliedly represented to be a controlled substance;

(2) is distributed under circumstances that would lead a reasonable person to believe that the substance is a controlled substance; or

(3) by overall dosage unit appearance, including shape, color, size, markings, or lack of markings, taste, consistency, or any other identifying physical characteristic of the substance, would lead a reasonable person to believe the substance is a controlled substance;
commits dealing in a substance represented to be a controlled substance, a Class D felony.

(b) In determining whether representations have been made, subject to subsection (a)(1), or whether circumstances of distribution exist, subject to subsection (a)(2), the trier of fact may consider, in addition to other relevant factors, the following:

(1) Statements made by the owner or other person in control of the substance, concerning the substance's nature, use, or effect.

(2) Statements made by any person, to the buyer or recipient of the substance, that the substance may be resold for profit.

(3) Whether the substance is packaged in a manner uniquely used for the illegal distribution of controlled substances.

(4) Whether:

(A) the distribution included an exchange of, or demand for, money or other property as consideration; and

(B) the amount of the consideration was substantially greater than the reasonable retail market value of the substance.

As added by Acts 1981, P.L.305, SEC.1. Amended by P.L.210-1986, SEC.1; P.L.165-1990, SEC.7.

IC 35-48-4-4.6

Sec. 4.6. (a) A person who knowingly or intentionally:

(1) manufactures;

(2) finances the manufacture of;

(3) advertises;

(4) distributes; or

(5) possesses with intent to manufacture, finance the manufacture of, advertise, or distribute;
a substance described in section 4.5 of this chapter commits a Class C felony.

(b) A person who knowingly or intentionally possesses a substance described in section 4.5 of this chapter commits a Class C misdemeanor. However, the offense is a Class A misdemeanor if the

person has a previous conviction under this section.

(c) In any prosecution brought under this section it is not a defense that the person believed the substance actually was a controlled substance.

(d) This section does not apply to the following:

(1) The manufacture, financing the manufacture of, processing, packaging, distribution, or sale of noncontrolled substances to licensed medical practitioners for use as placebos in professional practice or research.

(2) Persons acting in the course and legitimate scope of their employment as law enforcement officers.

(3) The retention of production samples of noncontrolled substances produced before September 1, 1986, where such samples are required by federal law.

(e) In addition to any other penalty imposed for conviction of an offense under this section, a court shall order restitution pursuant to IC 35-50-5-3 to cover the costs of an environmental cleanup incurred by a law enforcement agency or other person as a result of the offense.

(f) The amount collected under subsection (e) shall be used to reimburse the law enforcement agency that assumed the costs associated with the environmental cleanup described in subsection (e).

As added by P.L.210-1986, SEC.2. Amended by P.L.165-1990, SEC.8; P.L.150-1999, SEC.1.

IC 35-48-4-4.1

Sec. 4.1. (a) A person who dumps, discharges, discards, transports, or otherwise disposes of:

(1) chemicals, knowing the chemicals were used in the illegal manufacture of a controlled substance or an immediate precursor; or

(2) waste, knowing that the waste was produced from the illegal manufacture of a controlled substance or an immediate precursor;

commits dumping controlled substance waste, a Class D felony.

(b) It is not a defense in a prosecution under subsection (a) that the person did not manufacture the controlled substance or immediate precursor.

As added by P.L.17-2001, SEC.23.

IC 35-48-4-5

Sec. 5. A person who:

(1) knowingly or intentionally:

(A) creates;

(B) delivers; or

(C) finances the delivery of;

a counterfeit substance; or

(2) possesses, with intent to:

(A) deliver; or

(B) finance the delivery of;

a counterfeit substance;

commits dealing in a counterfeit substance, a Class D felony.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.100; P.L.165-1990, SEC.9.

IC 35-48-4-6

Sec. 6. (a) A person who, without a valid prescription or order of a practitioner acting in the course of the practitioner's professional practice, knowingly or intentionally possesses cocaine (pure or adulterated), a narcotic drug (pure or adulterated) classified in schedule I or II, or methamphetamine (pure or adulterated) commits possession of cocaine, a narcotic drug, or methamphetamine, a Class D felony, except as provided in subsection (b).

(b) The offense is:

(1) a Class C felony if:

(A) the amount of the drug involved (pure or adulterated) weighs three (3) grams or more; or

(B) the person was also in possession of a firearm (as defined in IC 35-47-1-5);

(2) a Class B felony if the person in possession of the cocaine, narcotic drug, or methamphetamine possesses less than three (3) grams of pure or adulterated cocaine, a narcotic drug, or methamphetamine:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center; and

(3) a Class A felony if the person possesses the cocaine, narcotic drug, or methamphetamine in an amount (pure or adulterated) weighing at least three (3) grams:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.101; Acts 1979, P.L.303, SEC.10; P.L.138-1983, SEC.3; P.L.296-1987, SEC.9; P.L.296-1995, SEC.7; P.L.65-1996, SEC.15; P.L.188-1999, SEC.7; P.L.17-2001, SEC.24.

IC 35-48-4-7

Sec. 7. (a) A person who, without a valid prescription or order of a practitioner acting in the course of his professional practice, knowingly or intentionally possesses a controlled substance (pure or adulterated) classified in schedule I, II, III, or IV, except marijuana or hashish, commits possession of a controlled substance, a Class D felony. However, the offense is a Class C felony if the person in possession of the controlled substance possesses the controlled substance:

(1) on a school bus; or

(2) in, on, or within one thousand (1,000) feet of:

(A) school property;

(B) a public park;

(C) a family housing complex; or

(D) a youth program center.

(b) A person who, without a valid prescription or order of a practitioner acting in the course of his professional practice, knowingly or intentionally obtains:

(1) more than four (4) ounces of schedule V controlled substances containing codeine in any given forty-eight (48) hour period unless pursuant to a prescription;

(2) a schedule V controlled substance pursuant to written or verbal misrepresentation; or

(3) possession of a schedule V controlled substance other than by means of a prescription or by means of signing an exempt narcotic register maintained by a pharmacy licensed by the Indiana state board of pharmacy; commits a Class D felony.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.102; P.L.138-1983, SEC.4; P.L.327-1985, SEC.4; P.L.296-1987, SEC.10; P.L.296-1995, SEC.8; P.L.65-1996, SEC.16; P.L.17-2001, SEC.25.

IC 35-48-4-8

(Repealed by Acts 1980, P.L.115, SEC.5.)

IC 35-48-4-8.1

Sec. 8.1. (a) A person who manufactures, finances the manufacture of, or designs an instrument, a device, or other object that is intended to be used primarily for:

(1) introducing into the human body a controlled substance;

(2) testing the strength, effectiveness, or purity of a controlled substance; or

(3) enhancing the effect of a controlled substance;

in violation of this chapter commits a Class A infraction for manufacturing paraphernalia.

(b) A person who:
(1) knowingly or intentionally violates this section; and
(2) has a previous judgment for violation of this section;
commits manufacture of paraphernalia, a Class D felony.
As added by Acts 1980, P.L.115, SEC.2. Amended by P.L.202-1989, SEC.3; P.L.165-1990, SEC.10.

IC 35-48-4-8.2
(*Repealed by P.L.1-1991, SEC.205.)*

IC 35-48-4-8.3
Sec. 8.3. (a) A person who possesses a raw material, an instrument, a device, or other object that the person intends to use for:
(1) introducing into the person's body a controlled substance;
(2) testing the strength, effectiveness, or purity of a controlled substance; or
(3) enhancing the effect of a controlled substance;
in violation of this chapter commits a Class A infraction for possessing paraphernalia.
(b) A person who:
(1) knowingly or intentionally violates subsection (a); and
(2) has a previous judgment or conviction under this section;
commits possession of paraphernalia, a Class D felony.
(c) A person who recklessly possesses a raw material, an instrument, a device, or other object that is to be used primarily for:
(1) introducing into the person's body a controlled substance;
(2) testing the strength, effectiveness, or purity of a controlled substance; or
(3) enhancing the effect of a controlled substance;
in violation of this chapter commits reckless possession of paraphernalia, a Class A misdemeanor. However, the offense is a Class D felony if the person has a previous judgment or conviction under this section.
As added by Acts 1980, P.L.115, SEC.4. Amended by P.L.202-1989, SEC.5; P.L.166-1990, SEC.2.

IC 35-48-4-8.5
Sec. 8.5. (a) A person who keeps for sale, offers for sale, delivers, or finances the delivery of a raw material, an instrument, a device, or other object that is intended to be or that is designed or marketed to be used primarily for:
(1) ingesting, inhaling, or otherwise introducing into the human body marijuana, hash oil, hashish, or a controlled substance;
(2) testing the strength, effectiveness, or purity of marijuana, hash oil, hashish, or a controlled substance;
(3) enhancing the effect of a controlled substance;
(4) manufacturing, compounding, converting, producing, processing, or preparing marijuana, hash oil, hashish, or a controlled substance;
(5) diluting or adulterating marijuana, hash oil, hashish, or a controlled substance by individuals; or
(6) any purpose announced or described by the seller that is in violation of this chapter;
commits a Class A infraction for dealing in paraphernalia.
(b) A person who:
(1) knowingly or intentionally violates subsection (a); and
(2) has a previous judgment or conviction under this section;
commits dealing in paraphernalia, a Class D felony.
(c) A person who recklessly keeps for sale, offers for sale, or delivers an instrument, a device, or other object that is to be used primarily for:
(1) ingesting, inhaling, or otherwise introducing into the human body marijuana, hash oil, hashish, or a controlled substance;
(2) testing the strength, effectiveness, or purity of marijuana, hash oil, hashish, or a controlled substance;
(3) enhancing the effect of a controlled substance;
(4) manufacturing, compounding, converting, producing, processing, or preparing marijuana, hash oil, hashish, or a controlled substance;
(5) diluting or adulterating marijuana, hash oil, hashish, or a controlled substance by individuals; or
(6) any purpose announced or described by the seller that is in violation of this chapter;
commits reckless dealing in paraphernalia, a Class A misdemeanor. However, the offense is a Class D felony if the person has a previous judgment or conviction under this section.
(d) This section does not apply to the following:
(1) Items marketed for use in the preparation, compounding, packaging, labeling, or other use of marijuana, hash oil, hashish, or a controlled substance as an incident to lawful research, teaching, or chemical analysis and not for sale.
(2) Items marketed for or historically and customarily used in connection with the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, or inhaling of tobacco or any other lawful substance.
As added by P.L.1-1991, SEC.206.

IC 35-48-4-9
(*Repealed by Acts 1980, P.L.115, SEC.5.)*

IC 35-48-4-10
Sec. 10. (a) A person who:
(1) knowingly or intentionally:
(A) manufactures;
(B) finances the manufacture of;
(C) delivers; or
(D) finances the delivery of;
marijuana, hash oil, or hashish, pure or adulterated; or
(2) possesses, with intent to:
(A) manufacture;
(B) finance the manufacture of;
(C) deliver; or
(D) finance the delivery of;
marijuana, hash oil, or hashish, pure or adulterated;
commits dealing in marijuana, hash oil, or hashish, a Class A misdemeanor, except as provided in subsection (b).
(b) The offense is:
(1) a Class D felony if:
(A) the recipient or intended recipient is under eighteen (18) years of age;
(B) the amount involved is more than thirty (30) grams but less than ten (10) pounds of marijuana or two (2) grams but less than three hundred (300) grams of hash oil or hashish; or
(C) the person has a prior conviction of an offense involving marijuana, hash oil, or hashish; and
(2) a Class C felony if the amount involved is ten (10) pounds or more of marijuana or three hundred (300) or more grams of hash oil or hashish or the person delivered or financed the delivery of marijuana, hash oil, or hashish:
(A) on a school bus; or
(B) in, on, or within one thousand (1,000) feet of:
(i) school property;
(ii) a public park;
(iii) a family housing complex; or
(iv) a youth program center.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.105; Acts 1979, P.L.303, SEC.11; Acts 1982, P.L.204, SEC.38; P.L.296-1987, SEC.11; P.L.165-1990, SEC.12; P.L.296-1995, SEC.9; P.L.65-1996, SEC.17; P.L.17-2001, SEC.26.

IC 35-48-4-11
Sec. 11. A person who:
(1) knowingly or intentionally possesses (pure or adulterated) marijuana, hash oil, or hashish;

(2) knowingly or intentionally grows or cultivates marijuana; or

(3) knowing that marijuana is growing on his premises, fails to destroy the marijuana plants;

commits possession of marijuana, hash oil, or hashish, a Class A misdemeanor. However, the offense is a Class D felony (i) if the amount involved is more than thirty (30) grams of marijuana or two (2) grams of hash oil or hashish, or (ii) if the person has a prior conviction of an offense involving marijuana, hash oil, or hashish.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.106; Acts 1979, P.L.303, SEC.12; P.L.138-1983, SEC.5.

IC 35-48-4-12

Sec. 12. If a person who has no prior conviction of an offense under this article or under a law of another jurisdiction relating to controlled substances pleads guilty to possession of marijuana or hashish as a Class A misdemeanor, the court, without entering a judgment of conviction and with the consent of the person, may defer further proceedings and place him in the custody of the court under such conditions as the court determines. Upon violation of a condition of the custody, the court may enter a judgment of conviction. However, if the person fulfills the conditions of the custody, the court shall dismiss the charges against him. There may be only one (1) dismissal under this section with respect to a person.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.107.

IC 35-48-4-13

Sec. 13. (a) A person who knowingly or intentionally visits a building, structure, vehicle, or other place that is used by any person to unlawfully use a controlled substance commits visiting a common nuisance, a Class B misdemeanor.

(b) A person who knowingly or intentionally maintains a building, structure, vehicle, or other place that is used one (1) or more times:

(1) by persons to unlawfully use controlled substances; or

(2) for unlawfully:

(A) manufacturing;

(B) keeping;

(C) offering for sale;

(D) selling;

(E) delivering; or

(F) financing the delivery of;

controlled substances, or items of drug paraphernalia as described in IC 35-48-4-8.5;

commits maintaining a common nuisance, a Class D felony.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.108; P.L.210-1986, SEC.4; P.L.165-1990, SEC.13; P.L.1-1991, SEC.207; P.L.31-1998, SEC.11; P.L.17-2001, SEC.27.

IC 35-48-4-14

Sec. 14. (a) A person who:

(1) is subject to IC 35-48-3 and who recklessly, knowingly, or intentionally distributes or dispenses a controlled substance in violation of IC 35-48-3;

(2) is a registrant and who recklessly, knowingly, or intentionally:

(A) manufactures; or

(B) finances the manufacture of;

a controlled substance not authorized by his registration or distributes or dispenses a controlled substance not authorized by his registration to another registrant or other authorized person;

(3) recklessly, knowingly, or intentionally fails to make, keep, or furnish a record, a notification, an order form, a statement, an invoice, or information required under this article; or

(4) recklessly, knowingly, or intentionally refuses entry into any premises for an inspection authorized by this article;

commits a Class D felony.

(b) A person who knowingly or intentionally:

(1) distributes as a registrant a controlled substance classified in schedule I or II, except under an order form as required by IC 35-48-3;

(2) uses in the course of the:

(A) manufacture of;

(B) the financing of the manufacture of; or

(C) distribution of;

a controlled substance a federal or state registration number that is fictitious, revoked, suspended, or issued to another person;

(3) furnishes false or fraudulent material information in, or omits any material information from, an application, report, or other document required to be kept or filed under this article; or

(4) makes, distributes, or possesses a punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or a likeness of any of the foregoing on a drug or container or labeling thereof so as to render the drug a counterfeit substance;

commits a Class D felony.

(c) A person who knowingly or intentionally acquires possession of a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, alteration of a prescription order, concealment of a material fact, or use of a false name or false address commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction of an offense under this subsection.

(d) A person who knowingly or intentionally affixes any false or forged label to a package or receptacle containing a controlled substance commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction of an offense under this subsection. This subsection does not apply to law enforcement agencies or their representatives while engaged in enforcing IC 16-42-19 or this chapter (or IC 16-6-8 before its repeal).

(e) A person who duplicates, reproduces, or prints any prescription pads or forms without the prior written consent of a practitioner commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction of an offense under this subsection. This subsection does not apply to the printing of prescription pads or forms upon a written, signed order placed by a practitioner or pharmacist, by legitimate printing companies.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.109; P.L.131-1986, SEC.3; P.L.165-1990, SEC.14; P.L.2-1993, SEC.193.

IC 35-48-4-14.5

Sec. 14.5. (a) As used in this section, "chemical reagents or precursors" refers to one (1) or more of the following:

(1) Ephedrine.

(2) Pseudoephedrine.

(3) Phenylpropanolamine.

(4) The salts, isomers, and salts of isomers of a substance identified in subdivisions (1) through (3).

(5) Anhydrous ammonia or ammonia solution (as defined in IC 22-11-20-1).

(6) Organic solvents.

(7) Hydrochloric acid.

(8) Lithium metal.

(9) Sodium metal.

(10) Ether.

(11) Sulfuric acid.

(12) Red phosphorous.

(13) Iodine.

(14) Sodium hydroxide (lye).

(15) Potassium dichromate.

(16) Sodium dichromate.

(17) Potassium permanganate.

(18) Chromium trioxide.

(b) A person who possesses anhydrous ammonia or ammonia solution (as defined in IC 22-11-20-1) with the intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6, commits a Class D felony. However, the offense is a Class C felony if the person possessed:

(1) a firearm while possessing anhydrous ammonia or ammonia

solution (as defined in IC 22-11-20-1) with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6; or

(2) anhydrous ammonia or ammonia solution (as defined in IC 22-11-20-1) with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6 in, on, or within one thousand (1,000) feet of:

(A) school property;

(B) a public park;

(C) a family housing complex; or

(D) a youth program center.

(c) A person who possesses two (2) or more chemical reagents or precursors with the intent to manufacture:

(1) Methcathinone, a schedule I controlled substance under IC 35-48-2-4;

(2) Methamphetamine, a schedule II controlled substance under IC 35-48-2-6;

(3) Amphetamine, a schedule II controlled substance under IC 35-48-2-6; or

(4) Phentermine, a schedule IV controlled substance under IC 35-48-2-10;

commits a Class D felony.

(d) An offense under subsection (c) is a Class C felony if the person possessed:

(1) a firearm while possessing two (2) or more chemical reagents or precursors with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6; or

(2) two (2) or more chemical reagents or precursors with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6 in, on, or within one thousand (1,000) feet of:

(A) school property;

(B) a public park;

(C) a family housing complex; or

(D) a youth program center.

As added by P.L.150-1999, SEC.2. Amended by P.L.17-2001, SEC.28.

IC 35-48-4-15

Sec. 15. (a) If a person is convicted of an offense under section 1, 2, 3, 4, 5, 6, 7, 10, or 11 of this chapter, or conspiracy to commit an offense under section 1, 2, 3, 4, 5, 6, 7, 10, or 11 of this chapter, the court shall, in addition to any other order the court enters, order that the person's:

(1) operator's license be suspended;

(2) existing motor vehicle registrations be suspended; and

(3) ability to register motor vehicles be suspended;

by the bureau of motor vehicles for a period specified by the court of at least six (6) months but not more than two (2) years.

(b) If a person is convicted of an offense described in subsection (a) and the person does not hold an operator's license or a learner's permit, the court shall order that the person may not receive an operator's license or a learner's permit from the bureau of motor vehicles for a period of not less than six (6) months.

As added by P.L.67-1990, SEC.13. Amended by P.L.107-1991, SEC.3; P.L.129-1993, SEC.2; P.L.64-1994, SEC.6.

IC 35-48-4-16

Sec. 16. (a) For an offense under this chapter that requires proof of:

(1) delivery of cocaine, a narcotic drug, methamphetamine, or a controlled substance;

(2) financing the delivery of cocaine, a narcotic drug, methamphetamine, or a controlled substance; or

(3) possession of cocaine, narcotic drug, methamphetamine, or controlled substance;

within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center, the person charged may assert the defense in subsection (b) or (c).

(b) It is a defense for a person charged under this chapter with an offense that contains an element listed in subsection (a) that:

(1) a person was briefly in, on, or within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center; and

(2) no person under eighteen (18) years of age at least three (3) years junior to the person was in, on, or within one thousand (1,000) feet of the school property, public park, family housing complex, or youth program center at the time of the offense.

(c) It is a defense for a person charged under this chapter with an offense that contains an element listed in subsection (a) that a person was in, on, or within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center at the request or suggestion of a law enforcement officer or an agent of a law enforcement officer.

(d) The defense under this section applies only to the element of the offense that requires proof that the delivery, financing of the delivery, or possession of cocaine, a narcotic drug, methamphetamine, or a controlled substance occurred in, on, or within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center.

As added by P.L.17-2001, SEC.29.

IC 35-48-7

Chapter 7. Central Repository for Controlled Substances Data

IC 35-48-7-1

Sec. 1. As used in this chapter, "advisory committee" refers to the controlled substances advisory committee established by IC 35-48-2-1.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-2

Sec. 2. As used in this chapter, "central repository" refers to the central repository designated by the state police department under section 10 of this chapter.

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.1.

IC 35-48-7-3

Sec. 3. As used in this chapter, "dispenser" has the meaning set forth in IC 35-48-1-13. However, the term does not include the following:

(1) A Type II pharmacy (as defined in IC 25-26-13-17) operated by a hospital licensed under IC 16-21.

(2) A nurse registered or licensed under IC 25-23 or a medication aide who administers a controlled substance at the direction of a physician licensed under IC 25-22.5.

(3) A person who administers or dispenses a controlled substance ordered for a bona fide patient in a facility licensed under IC 16-28.

(4) A pharmacy licensed under IC 25-26-13 when it dispenses prescriptions ordered for bona fide enrolled patients in facilities licensed under IC 16-28.

(5) A practitioner who dispenses not more than a forty-eight (48) hour supply of a controlled substance listed in either schedule II, III, or IV as set forth in IC 35-48-3-9.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-4

Sec. 4. As used in this chapter, "exception report" means a record of data concerning:

(1) a practitioner practicing a particular specialty or field of health care;

(2) a dispenser doing business in a particular location; or

(3) a recipient;

that indicates dispensing or receiving of controlled substances outside norms for dispensing or receiving controlled substances established by the advisory committee under this chapter.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-5

Sec. 5. As used in this chapter, "identification number" refers to the unique number contained on any of the following:

(1) A valid driver's license of a recipient or a recipient's representative issued under Indiana law or the law of any other state.

(2) A recipient's or a recipient representative's valid military identification card.

(3) A valid identification card of a recipient or a recipient's representative issued by:

(A) the bureau of motor vehicles and described in IC 9-24-16-3; or

(B) any other state and that is similar to the identification card issued by the bureau of motor vehicles.

(4) If the recipient is an animal:

(A) the valid driver's license issued under Indiana law or the law of any other state;

(B) the valid military identification card; or

(C) the valid identification card issued by the bureau of motor vehicles and described in IC 9-24-16-3 or a valid identification card of similar description that is issued by any other state;

of the animal's owner.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-6

Sec. 6. As used in this chapter, "recipient" means an individual for whom a controlled substance is dispensed.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-7

Sec. 7. As used in this chapter, "recipient representative" means the individual to whom a controlled substance is dispensed if the recipient is either less than eighteen (18) years of age or unavailable to receive the controlled substance.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-8

Sec. 8. The state police department, with the approval of the advisory committee, shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the advisory committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the central repository the following information:

(A) The recipient's name.

(B) The recipient's or the recipient representative's identification number.

(C) The recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(2) The information required to be transmitted under this section must be transmitted not more than fifteen (15) days after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) an electronic device compatible with the receiving device of the central repository;

(B) a computer diskette;

(C) a magnetic tape; or

(D) a pharmacy universal claim form;

that meets specifications prescribed by the advisory committee.

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms and serially numbered prescription forms for any prescriptions written. The committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.2.

IC 35-48-7-9

Sec. 9. (a) The state police department or the central repository is responsible for the costs of the program, including the following costs:

(1) Telephone access charges, line charges, and switch charges for transmission of data by dispensers to the central repository.

(2) Purchase of modems and other hardware required for program participation.

(3) Software and software modifications to allow dispensers to participate in the program.

(b) A dispenser may not be penalized for failure to comply with the program if the state police department or the central repository cannot secure adequate funding to implement the program and cover the costs under subsection (a).

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.3.

IC 35-48-7-10

Sec. 10. (a) The state police department, with the advice of the advisory committee, shall designate a central repository for the collection of information transmitted under section 8 of this chapter.

(b) The central repository shall do the following:

(1) Create a data base for information required to be transmitted under section 8 of this chapter in the form required under rules adopted by the advisory committee, including search capability for the following:

(A) A recipient's name.

(B) A recipient's or recipient representative's identification number.

(C) A recipient's date of birth.

(D) The national drug code number of a controlled substance dispensed.

(E) The dates a controlled substance is dispensed.

(F) The quantities of a controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) A dispenser's United States Drug Enforcement Agency registration number.

(I) A prescriber's United States Drug Enforcement Agency registration number.

(J) Whether a prescription was transmitted to the pharmacist orally or in writing.

(2) Provide the state police department and the advisory committee with continuing twenty-four (24) hour a day on-line access to the data base maintained by the central repository.

(3) Secure the information collected by the central repository and the data base maintained by the central repository against access by unauthorized persons.

(4) If the relationship between the state police department and the central repository is terminated by statute, provide to the state police department and the advisory committee, within a reasonable time, all collected information and the data base maintained by the central

repository.

(c) The state police department, with the advice of the advisory committee, may execute a contract with a vendor designated by the state police department as the central repository under this section, or the state police department or advisory committee may act as the central repository under this chapter.

(d) The central repository may gather prescription data from the Medicaid retrospective drug utilization review program (DUR) established by IC 12-15-35.

(e) The state police department and the advisory committee may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the central repository.

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.4.

IC 35-48-7-11

Sec. 11. (a) Information received by the central repository under section 8 of this chapter is confidential.

(b) The advisory committee shall carry out a program to protect the confidentiality of the information described in subsection (a). The advisory committee may disclose the information to another person only under subsection (c), (d), or (f).

(c) The advisory committee may disclose confidential information described in subsection (a) to any person who is engaged in receiving, processing, or storing the information.

(d) The advisory committee may release confidential information described in subsection (a) to the following persons:

(1) A member of the board, the committee, or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves a controlled substance.

(3) A law enforcement officer who is:

(A) authorized by the state police department to receive information of the type requested;

(B) approved by the advisory committee to receive information of the type requested; and

(C) engaged in the investigation or prosecution of a violation under any state or federal law that involves a controlled substance.

(e) Before the advisory committee releases confidential information under subsection (d), the applicant must demonstrate to the advisory committee that:

(1) the applicant has reason to believe that a violation under any state or federal law that involves a controlled substance has occurred; and

(2) the requested information is reasonably related to the investigation, adjudication, or prosecution of the violation described in subdivision (1).

(f) The advisory committee may release to:

(1) a member of the board, the advisory committee, or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive the type of information released; and

(B) approved by the advisory committee to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(g) The information described in subsection (f) may not be released until it has been reviewed by a member of the advisory committee who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data and until that member has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (h).

(h) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (f) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law that involves a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(i) The advisory committee may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-12

Sec. 12. The advisory committee shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

(1) Information collection and retrieval procedures for the central repository, including the controlled substances to be included in the program required under section 8 of this chapter.

(2) Design for the creation of the data base required under section 10 of this chapter.

(3) Requirements for the development and installation of on-line electronic access by the advisory committee to information collected by the central repository.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8 of this chapter without a written prescription or on a form other than a form specified in section 8(4) of this chapter.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-13

Sec. 13. (a) The controlled substances data fund is established to fund the operation of the central repository. The fund shall be administered by the state police department.

(b) Expenses of administering the fund shall be paid from money in the fund. The fund consists of grants, public and private financial assistance, and licensure fees.

(c) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested.

(d) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.5.

IC 35-48-7-14

Sec. 14. A person who knowingly or intentionally violates this chapter commits a Class A misdemeanor.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-15

(*Repealed by P.L.214-2001, SEC.1.)*

End of section

TITLE 858 CONTROLLED SUBSTANCES ADVISORY COMMITTEE

ARTICLE 1. SCHEDULE II CONTROLLED SUBSTANCES

Rule 1. Multiple Copy Prescription Program

NOTE: IC 35-48-6 was repealed by P.L.2-1995, SECTION 140, effective May 5, 1995.

858 IAC 1-1-1 Definitions

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 16-6-8-2; IC 35-48

Sec. 1. (a) As used in this article, "act" means the Indiana Controlled Substances Act, IC 35-48 et seq.

(b) As used in this article, "administer" means the direct application of a Schedule II controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(1) a prescriber or by an authorized agent of the prescriber; or

(2) the patient or research subject at the direction and in the presence of the prescriber.

(c) As used in this article, "bureau" means the health professions bureau.

(d) As used in this article, "committee" means the controlled substances advisory committee.

(e) As used in this article, "controlled substances registration (CSR)" means the Indiana registration issued to qualified applicants pursuant to IC 35-48-3.

(f) As used in this article, "delivery" means an actual or constructive transfer from one (1) person to another of a Schedule II controlled substance, whether or not there is an agency relationship.

(g) As used in this article, "dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a prescriber; and includes the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(h) As used in this article, "drug order" has the meaning set forth in IC 16-6-8-2(e).

(i) As used in this article, "institutional prescriber" means an individual practitioner who is an intern, resident, or foreign trained physician authorized to administer, prescribe, dispense, or deliver Schedule II controlled substances under the Drug Enforcement Administration registration of the hospital or other training institution which is registered and by whom the institutional prescriber is employed.

(j) As used in this article, "multiple copy prescription form" means the official prescription form issued by the health professions bureau utilized to administer, dispense, prescribe, or deliver a Schedule II controlled substance to an ultimate user.

(k) As used in this article, "prescriber" means a physician, dentist, podiatrist, institutional prescriber, or veterinarian, who issues a prescription.

(l) As used in this article, "prescription" has the meaning set forth in IC 16-6-8-2(d).

(m) As used in this article, "Schedule II controlled substance" means:

(1) a controlled substance classified in Schedule II under IC 35-48-2-6; or

(2) a controlled substance classified in Schedule II by rule adopted pursuant to IC 35-48-2-14.

(n) As used in this article, "small amounts" means single dosage amounts as specified in the manufacturer's package insert.

(o) As used in this article, "ultimate user" means a person who lawfully possesses a Schedule II controlled substance for his or her own use or for the use of a member of his or her household or for administering to an animal owned by him or her or by a member of that household. (Controlled Substances Advisory Committee; 858 IAC 1-1-1; filed Jul 28, 1988, 2:12 p.m.: 11 IR 4104; filed Jun 14, 1989, 10:45 a.m.: 12 IR 2058)

858 IAC 1-1-2 Official multiple copy prescription forms

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 35-48-6

Sec. 2. (a) Official multiple copy prescription forms shall be supplied in serially numbered groups, each in triplicate, and furnished to prescribers at no charge.

(b) Official multiple copy prescription forms shall be imprinted with the prescriber's name, address and drug enforcement administration registration number. (Controlled Substances Advisory Committee; 858 IAC 1-1-2; filed Jul 28, 1988, 2:12 pm: 11 IR 4104)

858 IAC 1-1-3 Applicability

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 35-48-6

Sec. 3. These rules (858 IAC 1-1) and the multiple copy prescription program shall apply only to Schedule II controlled substances, and shall not apply to Schedule III, IV, or V controlled substances, nor to any other drug. (Controlled Substances Advisory Committee; 858 IAC 1-1-3; filed Jul 28, 1988, 2:12 pm: 11 IR 4105)

858 IAC 1-1-4 Use of multiple copy prescription forms

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 25-26-13-16; IC 35-48-6

Sec. 4. (a) Every prescriber who administers, dispenses, prescribes, or delivers any quantity of a controlled substance in Schedule II must complete a multiple copy prescription form, by filling in the spaces provided. The required information on each individual patient receiving the controlled substance or controlled substance prescription will be recorded as follows:

(1) Date the prescription is written (cannot be postdated).
(2) Name of the patient (or in case of an animal, its owner).
(3) Address of patient (or in case of an animal, its owner).
(4) In the case of an animal, its species.
(5) Date of birth (or in the case of an animal, its approximate age).
(6) Name and strength or size of the drug prescribed.
(7) Amount of drug to be dispensed.
(8) Adequate directions for the proper use of the drug. (Stamped or preprinted directions are permitted; however, the directions must be legible and appear on all copies.)
(9) Sign in the proper signature block advising the pharmacist/pharmacy of one (1) of the following:
(A) "Dispense as Written".
(B) "May Substitute".

The prescription shall be signed by the prescriber in the same manner as the prescriber would sign a check or legal document.

(b) Only a single prescription may be written on a multiple copy prescription form; however, if the same controlled substance is both administered and dispensed to the same patient by a prescriber, the prescriber may record the total dosage dispensed and administered on a single multiple copy form.

(c) When a prescriber administers and/or dispenses directly to a patient, the prescriber shall:

(1) check the appropriate "Administered or Dispensed Directly to the Patient" block; and

(2) sign the completed multiple copy prescription form in the "Dispense as Written" signature block.

(d) When a prescriber administers and/or dispenses directly to a patient, the completed multiple copy prescription form shall be

processed as follows: Copies 1 and 2 must be sent to the Health Professions Bureau, Multiple Copy Prescription Division, One American Square, Suite 1020, Box 82067, Indianapolis, Indiana 46282. These copies must be forwarded to the bureau by the fifteenth day of the month following the month in which the prescription is administered or dispensed.

(e) When it is not desirable to issue a multiple copy prescription form for each administration, dispensing, or topical application of small amounts of Schedule II controlled substances for minor office procedures, information must be recorded on the multiple copy prescription form as follows:

(1) Maintain a list of all patients to whom a Schedule II controlled substance was dispensed, administered, or topically applied in small amounts. This list shall include the patient's true name, current address, and date of birth as required in subsection (a).

(2) The complete list, along with copy 1 and copy 2 of a multiple copy prescription form, must be submitted to the health professions bureau, multiple copy division, by the fifteenth day of the month following the month of the patient's visit to the prescriber's office.

(3) A separate multiple copy prescription form and list will be required for each drug administered, and the multiple copy prescription form will be completed as follows:

(A) "See attached list" will be placed in the space provided for the patient's name.

(B) The total amount of Schedule II controlled substance administered for the reported month (or reporting period) along with the total number of patients on the attached list. (Example: 10cc's of 4% cocaine solution administered to 65 patients.)

(C) In "Date Issued" space, record the month and year. (Example: January 1989, February 1989, etc.)

(D) The prescriber will sign the completed multiple copy prescription form in the appropriate space and check the "Administered" box indicating the medication was administered directly to the patient.

(E) Attach copy 1 and copy 2 to the patient name list and submit as outlined in subdivision (2).

(f) When a prescriber issues a prescription for a Schedule II controlled substance to a patient, the format set out in subsection (d) shall be followed except:

(1) the "Administered or Dispensed Directly to Patient by Prescriber" blocks will be disregarded; and

(2) detached copies 1 and 2 will be given to the patient to take to the pharmacy to be filled.

(g) Copy 3 of the multiple copy prescription form may remain with the prescriber.

(h) In the event that a pharmacist receives a multiple copy prescription form written for a legend drug other than a Schedule II controlled substance, the pharmacist shall mark the prescription in such a way as to alert personnel of the bureau's multiple copy division that the drug is not a Schedule II controlled substance and shall submit it to the bureau by the fifteenth day of the month following the month in which it was filled.

(i) A multiple copy prescription form shall not be issued by a prescriber for the purpose of obtaining Schedule II controlled substances for office use. (Controlled Substances Advisory Committee; 858 IAC 1-1-4; filed Jul 28, 1988, 2:12 p.m.: 11 IR 4105; filed Jun 14, 1989, 10:45 a.m.: 12 IR 2059)

858 IAC 1-1-5 Emergency use of Schedule II controlled substances

Authority: IC 35-48-6-6; IC 35-48-6-11

Affected: IC 35-48-6

Sec. 5. (a) No prescriber shall issue a prescription for a Schedule II controlled substance other than on the multiple copy prescription form issued by the bureau and no pharmacist shall fill any such prescription other than on the multiple copy prescription form. However, in the case of an emergency situation, the prescriber may issue a lawful oral prescription or a written prescription on a form other than the multiple copy prescription form.

(b) For purposes of authorizing oral prescriptions or prescriptions on forms other than the multiple copy prescription forms "emergency situation" means those situations in which the prescriber determines that:

(1) immediate administration of the Schedule II controlled substance is necessary for the proper treatment of the intended ultimate user;

(2) no appropriate alternative treatment is available, including administration of a drug which is not a Schedule II controlled substance; and

(3) it is not reasonably possible for the prescriber to provide a written prescription on the multiple copy prescription form to a pharmacist prior to the dispensing.

(c) Within seventy-two (72) hours after issuing an emergency prescription, the prescriber shall cause a written prescription on the multiple copy prescription form for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face "Authorization for Emergency Dispensing", and the date of the emergency prescription.

(d) Upon receipt, the dispensing pharmacist shall attach the multiple copy prescription form to the emergency prescription earlier received, or in the case of an oral prescription, the document on which it was reduced to writing. (Controlled Substances Advisory Committee; 858 IAC 1-1-5; filed Jul 28, 1988, 2:12 pm: 11 IR 4105)

858 IAC 1-1-6 Application for multiple copy prescription form

Authority: IC 35-48-6-6; IC 35-48-6-11

Affected: IC 35-48-6

Sec. 6. (a) Applications for multiple copy prescription forms may be submitted by a qualified licensed prescriber possessing a valid controlled substances registration and Drug Enforcement Administration registration. Applications may also be submitted by institutional prescribers as defined in section 1 of this rule, provided that as follows:

(1) Administration, prescribing, dispensing, or delivery of Schedule II controlled substance is done in the usual course of the institutional prescriber's training, teaching program, or employment, at such hospital or training program.

(2) A specific internal code number as provided for in 856 IAC 2-3-5(c)(5) has been assigned to the individual by the authorizing hospital or training program.

(3) A current list of these prescribers and their institutional permit numbers is maintained by the hospital or training institution. This list shall be provided by the institution or training program to the health professions bureau, multiple copy division, and shall be made available to the public upon request for the purpose of verifying the authority of the prescribing individual practitioner.

(b) The committee shall make the applications available upon the prescriber's request. The completed application shall contain the following:

(1) Prescriber's name and address. (This shall be the same address to which the Indiana controlled substances registration is issued.)

(2) Prescriber's telephone number.

(3) Professional activity (e.g., M.D., D.V.M.).

(4) A statement as to whether any professional license or controlled substances registration ever held by the prescriber has been surrendered, revoked, denied or has action pending.

(5) A statement as to whether the prescriber has been convicted of or has pled nolo contendere to a crime (other than a traffic violation).

(6) The specialty or type of practice in which the prescriber is engaged.

(7) The legal signature of the prescriber.

(c) The bureau shall supply the multiple copy prescription forms within thirty (30) days of receipt of the application unless one (1) or more of the following situations exist:

(1) The prescriber has an expired, suspended, revoked, or surrendered professional license.

(2) The prescriber has a limited, expired, suspended, revoked, or surrendered Indiana controlled substances registration.

(3) The prescriber has an expired, suspended, revoked or surrendered Drug Enforcement Administration registration.

(4) The name and address of the prescriber does not match that appearing on the Indiana controlled substances registration or the Drug Enforcement Administration registration.

(5) The application does not bear the signature of the prescriber.

(6) The prescriber has not provided all required information.

(Controlled Substances Advisory Committee; 858 IAC 1-1-6; filed Jul 28, 1988, 2:12 p.m.: 11 IR 4106; filed Jun 14, 1989, 10:45 a.m.: 12 IR 2060)

858 IAC 1-1-7 Emergency application for multiple copy prescription forms

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 35-48-6

Sec. 7. (a) A prescriber holding a valid CSR may issue an emergency prescription for a Schedule II controlled substance by oral or telephonic means in accordance with 858 IAC 1-1-5. If this situation occurs and the prescriber is not in possession of imprinted multiple copy prescription forms, the prescriber may order such forms, in limited quantity, on an emergency basis under the following terms and conditions:

(1) the prescriber shall contact the bureau to request an emergency supply of multiple copy prescription forms;

(2) the bureau may take steps to certify the identity of the requesting prescriber;

(3) the bureau shall forward five (5) blank multiple copy prescription forms to the prescriber in a manner that allows the prescriber to comply with the seventy-two (72) hour requirement of 858 IAC 1-1-5.

(b) Upon receipt of the blank multiple forms the prescriber shall forward a completed application for the preprinted multiple copy prescription forms to the Health Professions Bureau. (Controlled Substances Advisory Committee; 858 IAC 1-1-7; filed Jul 28, 1988, 2:12 pm: 11 IR 4106)

858 IAC 1-1-8 Pharmacist responsibility

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 35-48-6

Sec. 8. (a) Upon receipt of copy 1 and 2 of a properly completed multiple copy prescription form from a prescriber, each dispensing pharmacist shall utilize the “Pharmacy Use Only” section of the form and record the following:

(1) Pharmacy name, address, telephone number, and Drug Enforcement Administration number. This information may be printed, typed, or rubber stamped, or the pharmacist may use a label that is securely affixed in this area.

(2) The actual signature of the dispensing pharmacist shall be entered in a space located directly below the pharmacy information.

(3) Enter in the spaces provided the date filled and the pharmacy prescription number.

(4) Ensure that the drug prescribed and/or its substitute is legible on copy 1 of the multiple copy prescription form.

(b) The pharmacist shall forward copy 2 of the prescription to the bureau by the fifteenth day of the month following the month in which the prescription was filled.

(c) Should a prescription be written on a multiple copy prescription form by a prescriber for a legend drug other than a Schedule II controlled substance, the pharmacist will be permitted to fill the prescription but will mark the prescription in such a way as to alert personnel of the bureau's multiple copy division that the drug is not a Schedule II.

(d) A pharmacist who dispenses a Schedule II controlled substance pursuant to an orally or telephonically communicated prescription or a prescription issued on a form other than the multiple copy prescription form from a prescriber for an emergency situation as defined in this rule, shall promptly reduce such prescription to writing to include the following:

(1) Name, address, and Federal Drug Enforcement Administration number of the prescriber issuing the prescription.

(2) Drug prescribed, the dosage, and instructions for use.

(3) Name, address, and date of birth of the person for whom the controlled substance is prescribed (or if an animal, the species, approximate age, and owner's name and address).

(e) If the prescriber fails to check the appropriate block at the bottom of the multiple copy form indicating that the prescription is an emergency order, the pharmacist should do so.

(f) The pharmacist shall attach copy 1 of the multiple copy prescription form to the oral emergency prescription which was reduced to writing upon receipt from the prescriber.

(g) A pharmacist may fill a prescription for a Schedule II controlled substance written by an out-of-state prescriber provided the pharmacist completes a pharmacy inventory control form. These completed forms shall be returned to the bureau by the fifteenth day of the month following the month in which the prescription was filled. (Controlled Substances Advisory Committee; 858 IAC 1-1-8; filed Jul 28, 1988, 2:12 p.m.: 11 IR 4107; filed Jun 14, 1989, 10:45 a.m.: 12 IR 2061)

858 IAC 1-1-9 Pharmacy inventory control form

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 35-48-6

Sec. 9. (a) A pharmacist may fill a prescription for a Schedule II controlled substance issued by an out-of-state prescriber provided the pharmacist completes a pharmacy inventory control form. This form may be obtained in the desired quantity from the Health Professions Bureau, One American Square, Suite 1020, Box 82067, Indianapolis, Indiana 46282 and shall be made available to a pharmacy licensed by the Indiana Board of Pharmacy.

(b) The original copies of the completed pharmacy inventory control forms shall be submitted to the multiple copy prescription division of the bureau by the fifteenth day of the month following the month in which the prescription was filled. (Controlled Substances Advisory Committee; 858 IAC 1-1-9; filed Jul 28, 1988, 2:12 p.m.: 11 IR 4107; filed Jun 14, 1989, 10:45 a.m.: 12 IR 2061)

858 IAC 1-1-10 Exemption for hospitals, hospital programs, and health facilities

Authority: IC 35-48-6-11
Affected: IC 16-10-4; IC 35-48-6

Sec. 10. (a) Use of a multiple copy prescription form is not required for the following:

(1) Drug orders written for use by or administration to a patient admitted to a hospital, ambulatory surgery center (if licensed in Indiana), or surgical suite in a dental school.

(2) Drug orders written for Schedule II controlled substances that are administered, dispensed, or ordered from a hospital pharmacy for a bona fide, enrolled patient in a hospital based program.

(3) Schedule II controlled substances administered, dispensed, or ordered for a bona fide, enrolled patient in a facility licensed under IC 16-10-4.

(b) No exemption is granted for prescriptions filled for outpatients or clients from a retail pharmacy within the hospital or health care facility. (Controlled Substances Advisory Committee; 858 IAC 1-1-10; filed Jul 28, 1988, 2:12 p.m.: 11 IR 4107; filed Jun 14, 1989, 10:45 a.m.: 12 IR 2061)

858 IAC 1-1-11 Confidentiality of information generated from computer records

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 35-48-6

Sec. 11. (a) Information generated from computer records compiled to initially identify prescribers or pharmacists prescribing or dispensing large quantities of a Schedule II controlled substance is confidential. The information leading to identification of these individuals may be released only to the following:

(1) a member of the board licensing and regulating the profession, the advisory committee, or another governing body that licenses the prescriber or pharmacist;

(2) an investigator for the consumer protection division of the office of the attorney general; and

(3) a law enforcement officer who is:

(A) employed by the Indiana State Police;

(B) authorized by the Indiana State Police to receive the type of information released; and

(C) approved by the advisory committee to receive the type of information released.

(b)(1) The information generated from computer records referred to in this section shall not be released until it has been reviewed by a member of the advisory committee who is licensed in the same profession as the prescriber or dispensing pharmacist identified by the data. The member of the advisory committee shall certify that further investigation is warranted. Prior to making this certification the member shall:

(A) take into consideration the specialty or type of practice of the prescriber or pharmacist;

(B) the geographic location of the prescriber's office or of the pharmacy; and

(C) the customary standard of practice within a locality.

(2) Prior to certifying that further investigation is warranted a reviewing member of the advisory committee may seek input from other prescribers specializing in similar type of practice and/or residing in a similar location. However, review of this information shall be of a general nature, shall remain confidential and shall not reveal the name of the prescriber, the dispensing pharmacist, or the name of the patient receiving the Schedule II controlled substance. (Controlled Substances Advisory Committee; 858 IAC 1-1-11; filed Jul 28, 1988, 2:12 pm: 11 IR 4108)

858 IAC 1-1-12 Effectiveness

Authority: IC 35-48-6-6; IC 35-48-6-11
Affected: IC 35-48-6

Sec. 12. This program applies to those prescriptions written on or after July 1, 1989. (Controlled Substances Advisory Committee; 858 IAC 1-1-12; filed Jul 28, 1988, 2:12 pm: 11 IR 4108)

ARTICLE 2. CONTROLLED SUBSTANCE MONITORING

Rule 1. Electronic Prescription Monitoring Program

858 IAC 2-1-1 Definitions

Authority: IC 35-48-7-12
Affected: IC 35-48-2-6; IC 35-48-2-14; IC 35-48-7-3

Sec. 1. (a) As used in this article, “department” refers to the Indiana state police department.

(b) As used in this article, “dispense” means the actual or constructive transfer from one (1) person to another whether or not there is an agency relationship.

(c) As used in this article, “dispenser” has the meaning set forth in IC 35-48-7-3.

(d) As used in this article, “Schedule II controlled substance” means:

(1) a controlled substance classified in Schedule II under IC 35-48-2-6; or

(2) a controlled substance classified in Schedule II by rule adopted under IC 35-48-2-14.

(e) As used in this article, “universal claim form” means a nationally recognized standard form developed by the National Council for Prescription Drug Programs used for billing drug claims to insurance plans. (Controlled Substances Advisory Committee; 858 IAC 2-1-1; filed Oct 6, 1994, 1:30 p.m.: 18 IR 266; filed Jan 27, 2000, 7:49 a.m.: 23 IR 1383; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)

858 IAC 2-1-2 Applicability

Authority: IC 35-48-7-12
Affected: IC 35-48-7-8

Sec. 2. This article shall apply only to Schedule II controlled substances and shall not apply to Schedule III, IV, or V controlled substances, nor to any other drug. (Controlled Substances Advisory Committee; 858 IAC 2-1-2; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)

858 IAC 2-1-3 Prescription monitoring program

Authority: IC 35-48-7-12
Affected: IC 35-48-7-8

Sec. 3. (a) Each time a Schedule II controlled substance is dispensed, the dispenser shall transmit to the central repository information outlined in IC 35-48-7-8.

(b) Dispensers reporting more than twenty (20) Schedule II prescriptions in any given month must transmit to the central repository information outlined in IC 35-48-7-8 utilizing one (1) of the following:

(1) An electronic device compatible with the receiving device of the central repository.

(2) A computer diskette.

(3) A magnetic tape.

(c) Dispensers reporting less than twenty (20) Schedule II prescriptions in any given month may submit data utilizing a universal claim form or transmit the information utilizing the ways outlined in subsection (b).

(d) The committee may grant a waiver to a dispenser which is unable to transmit the required data in accordance with subsection (b) for a period of one hundred eighty (180) days from the effective date of this rule which one hundred eighty (180) day period may be extended by the committee at its discretion. During the effective period of the waiver and any extension granted by the committee, the dispenser shall submit the required data in a format acceptable to the committee. (Controlled Substances Advisory Committee; 858 IAC 2-1-3; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)

858 IAC 2-1-4 Application for payment of pharmacy costs

Authority: IC 35-48-7-12
Affected: IC 35-48-7-9

Sec. 4. (a) Before the department will pay for the purchase of hardware to comply with the program, an applicant must file an application provided by the department and provide the following information:

(1) The dispenser’s name, address, and Indiana license number.

(2) A detailed description of the dispenser's current computer hardware, including the name and manufacturer of all components.

(3) A detailed description of the hardware the dispenser intends to purchase and two (2) price quotes from computer hardware vendors.

(4) The reason why the dispenser believes the computer hardware will be necessary to comply with the program.

(5) The number of Schedule II prescriptions the pharmacy dispenses in any given month.

(b) Upon receipt of an application requesting that the department pay for computer hardware, the committee shall evaluate the dispenser's current technology in determining whether the dispenser would be required to purchase new computer hardware. The committee shall take into account the ability of the dispenser to utilize any one (1) of the methods outlined in section 3 of this rule.

(c) The central repository shall provide grants to software vendors to update software in order for dispensers to comply with the program as outlined in contract form.

(d) The department and the central repository shall pay for telephone access charges, line charges, and switch charges for transmission of data by dispensers to the central repository. (Controlled Substances Advisory Committee; 858 IAC 2-1-4; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; filed Jan 27, 2000, 7:49 a.m.: 23 IR 1384; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)

End of section.

ARTICLE 2. CONTROLLED SUBSTANCES

Rule 1. Definitions

856 IAC 2-1-1 Definitions

Authority: IC 35-48-3-1

Affected: IC 4-21.5; IC 35-48-2-1

Sec. 1. Definitions. As used herein, the following terms shall have the meanings specified:

(a) The term "Act" means the Indiana Uniform Controlled Substances Act of 1973. IC 1971, 35-24.1 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(b) The term "basic class" means, as to controlled substances listed in Schedules I and II [856 IAC 2-2-2 and 856 IAC 2-2-3]:

(1) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in Section 2.11(b) [856 IAC 2-2-2(b)] of this chapter;

(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in Section 2.11(c) [856 IAC 2-2-2(c)] of this part;

(3) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in Section 2.11(d) [856 IAC 2-2-2(d)] of this part;

(4) Each of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(i) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(ii) Apomorphine;

(iii) Codeine;

(iv) Ethylmorphine;

(v) Hydrocodone;

(vi) Hydromorphone;

(vii) Metopon;

(viii) Morphine;

(ix) Oxycodone;

(x) Oxymorphone;

(xi) Thebaine;

(xii) Mixed alkaloids of opium listed in Section 2.12(b)(2) [856 IAC 2-2-3(b)(2)] of this part;

(xiii) Cocaine; and

(xiv) Ecgonine;

(5) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, listed in Section 2.12(c) [856 IAC 2-2-3(c)] as amended, of this part;

(6) Methamphetamine, including salts, isomers, and salts of isomers.

(7) Amphetamine, its salts, optical isomers and salts of its optical isomers;

(8) Phenmetrazine and its salts; and

(9) Methylphenidate.

(c) The term "Administration" means the Drug Enforcement Administration, formerly the Bureau of Narcotics and Dangerous Drugs.

(d) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

(e) The term "controlled premises" means

(1) Places where original or other records or documents required under the Act [IC 35-48] are kept or required to be kept, and

(2) Places including factories, warehouses, or other establishments, conveyances, where persons registered under the Act [IC 35-48] or exempted from registration under the Act [IC 35-48] may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances.

(f) The term "Administrator" means the Director of the Federal Drug Enforcement Administration who has been delegated authority under the Controlled Substances Act of 1970 (84 Stat. 1242; 21 U.S.C. 801) by the Attorney General of the United States (28 C.F.R. 0.100), as amended.

(g) The term "hearing" means any hearing held pursuant to the provisions of IC 1971, 4-22-1 through 4-22-1-30 [Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.] as amended and 4-22-2, for the purpose of granting, denying, or revoking, or suspending a registrant or application for registrant or a hearing amending these rules pursuant to IC 1971, 35-24.1 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(h) The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted by the State of Indiana or the United States, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(i) The term "institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the state of Indiana or the United States, to dispense a controlled substance in the course of practice, but does not include a pharmacy.

(j) The term "person" includes any individual, corporation, government or governmental subdivision or agency, business, trust partnership, association or other legal entity.

(k) The term "pharmacist" means any practitioner licensed as a pharmacist by the State of Indiana to dispense controlled substances and shall include pharmacist interns licensed by the State of Indiana, to dispense controlled substances under the supervision of a pharmacist licensed by the State of Indiana.

(l) The term "prescription" means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

(m) The terms "register" and "registration" refers only to registration required and permitted by IC 1971, 35-24.1-3-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(n) The term "registrant" means any person who is registered or exempted from registration pursuant to IC 1971, 35-24.1-3-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(o) Any term not defined in this section shall have the definition set forth in IC 1971, 35-24.1-1-1 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-1-2 Controlled substances advisory committee; function; hearings

Authority: IC 35-48-3-1
Affected: IC 4-21.5; IC 35-48-2-1

Sec. 2. Function. The Controlled Substances Advisory Committee shall serve as a consultative and advisory body to the Board in all matters relative to additions, deletions and transfers of substances to or among schedules of control established by IC 1971, 35-24.1 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

In addition, the advisory committee may, as representatives of the Board, conduct hearings regarding control of substances, and it shall, as representatives of the Board, conduct hearings and make recommended findings in matters affecting the denial, suspension, or revocation of registrations. All adjudicatory hearings shall be conducted in a manner consistent with the provision of IC 1971, 35-24.1-3-4 through IC 1971, 35-24.1-3-5 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48], and IC 1971, 4-22-1 [Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.]as amended. (Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.11; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-1-3 Meetings; organization
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 3. Meetings and Organization. The controlled substances advisory committee shall meet not later than sixty (60) days after the appointment of their entire membership and thereafter shall meet upon the request of the Board. The committees shall select, from among their members, a chairman, vice-chairman, and secretary who shall serve terms of one year from the date of selection. In any case in which a committee officer shall be unable to serve a full term, the committee shall select another to serve in his own right a full term. (Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.12; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-1-4 Duties of officers
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 4. Duties of Officers. The chairman of the committee, or the vice-chairman in the absence of the chairman, shall preside at all meetings of the committee. In addition, the chairman or his designee shall preside over all hearings conducted by the committee on behalf of the Board.

The secretary of the committee shall be responsible for keeping the minutes of all meetings and he shall further be charged with the responsibility of assuring that a complete and accurate record is made of all hearings conducted before the committee. To this end, he may, with the consent of the Board, arrange for the attendance of such stenographers or court reporters as are necessary for the recording of such hearings. (Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.13; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-1-5 Rulemaking powers
Authority: IC 35-48-3-1
Affected: IC 4-22-2; IC 35-48-2-1

Sec. 5. Rules of Conduct. The advisory committee may, with the approval of the Board, make such other rules regulating its conduct and procedure as are necessary and proper for the orderly conduct of its business.

All such rules, when they may affect procedure or substance of matters which may come before the Board for adjudication, after promulgation in accordance with IC 1971, 4-22-2 as amended, shall be in writing and shall be made available upon request to parties appearing before the committee. (Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.14; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-1-6 Recommendations and findings
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 6. Recommendations and findings. Recommendations and findings to be in writing. Whenever, in the discharge of its duties, the advisory committee shall be required to make recommendations or findings upon matters heard before the committee, such recommendations to the Board shall be in writing and shall include a summary of relevant evidence, opinions, and laws upon which such recommendations or findings are based. (Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.15; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 2. Controlled Substances Code Number Schedules I through IV

856 IAC 2-2-1 Controlled substances code numbers
Authority: IC 35-48-3-1
Affected: IC 35-48-3-1

Sec. 1. Controlled Substances Code Number. (a) Each controlled substance, or basic class thereof, listed in Schedules I through IV [856 IAC 2-2-2 856 IAC 2-2-5] has been assigned a "Controlled Substances Code Number" for purposes of identification of the substances or class on certain Certificates of Registration issued by the Indiana State Board of Pharmacy pursuant to Section 3.42 [856 IAC 2-3-19] of the Chapter. Certain applicants for registration must include the appropriate numbers on the application as required in Section 3.32(d) [856 IAC 2-3-13(d)] of this Chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Controlled Substances Code Number for any purpose. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-2 Schedule I
Authority: IC 35-48-2-14; IC 35-48-3-1
Affected: IC 35-48-2-4

Sec. 2. (a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the controlled substances code number set forth opposite it.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol 9601
(2) Allylprodine 9602
(3) Alphacetylmethadol (except levo-alphalmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM) 9603
(4) Alphameprodine 9604
(5) Alphamethadol 9605
(6) Benzethidine 9606
(7) Betacetylmethadol 9607
(8) Betameprodine 9608
(9) Betamethadol 9609
(10) Betaprodine 9611

(11) Clonitazene 9612
(12) Dextromoramide 9613
(13) Dextrorphan 9614
(14) Diampromide 9615
(15) Diethylthiambutene 9616
(16) Difenoxin 9168
(17) Dimenoxadol 9617
(18) Dimepheptanol 9618
(19) Dimethylthiambutene 9619
(20) Dioxaphetyl butyrate 9621
(21) Dipipanone 9622
(22) Ethylmethylthiambutene 9623
(23) Etonitazene 9624
(24) Etoxeridine 9625
(25) Furethidine 9626
(26) Hydroxypethidine 9627
(27) Ketobemidone 9628
(28) Levomoramide 9629
(29) Levophenacylmorphan 9631
(30) Morpheridine 9632
(31) Noracymethadol 9633
(32) Norlevorphanol 9634
(33) Normethadone 9635
(34) Norpipanone 9636
(35) Phenadoxone 9637
(36) Phenampromide 9638
(37) Phenomorphan 9647
(38) Phenoperidine 9641
(39) Piritramide 9642
(40) Proheptazine 9643
(41) Properidine 9644
(42) Propiram 9649
(43) Racemoramide 9645
(44) Trimeperidine 9646

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetrophine 9319
(2) Acetyldihydrocodeine 9051
(3) Benzylmorphine 9052
(4) Codeine methylbromide 9070
(5) Codeine-N-Oxide 9053
(6) Cyprenorphine 9054
(7) Desomorphine 9055
(8) Dihydromorphine 9145
(9) Drotebanol 9335
(10) Etorphine (Except Hydrochloride Salt) 9056
(11) Heroin 9200
(12) Hydromorphinol 9301
(13) Methyldesorphine 9302
(14) Methylidihydromorphine 9304
(15) Morphine methylbromide 9305
(16) Morphine methylsufonate 9306
(17) Morphine-N-Oxide 9307
(18) Myrophine 9308
(19) Nicocodeine 9309
(20) Nicomorphine 9312
(21) Normorphine 9313
(22) Pholcodine 9314
(23) Thebacon 9315

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subsection only, "isomer" includes the optical, position, and geometric isomers):

(1) 4-Bromo-2, 5-Dimethoxyamphetamine 7391
Some trade or other names:
4-Bromo-2, 5-Dimethoxy-a-methylphenethylamine; 4-Bromo-2, 5-DMA

(2) 2, 5-Dimethoxyamphetamine 7396
Some trade or other names:
2, 5-Dimethoxy-a-methylphenethylamine; 2,5-DMA

(3) 4-Methoxyamphetamine 7411
Some trade or other names:
4-Methoxy-a-methylphenethylamine: Paramethoxyamphetamine: PMA

(4) 5-methoxy-3, 4-methylenedioxy amphetamine 7401

(5) 4-methyl-2, 5-dimethoxyamphetamine 7395
Some trade and other names:
4-methyl-2,5-dimethoxy-a-methylphenethylamine: "DOM"; and "STP".

(6) 3, 4-methylenedioxy amphetamine 7400

(7) 3, 4, 5-trimethoxy amphetamine 7390

(8) Bufotenine 7433
Some trade and other names:
3-(B-Dimethylaminoethyl)-5-hydroxyindol; 3-(2-Dimethylaminoethyl)-5-indolo; N, N-dimenthylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine.

(9) Diethyltryptamine 7434
Some trade and other names: N, N-Diethyltryptamine, DET.

(10) Dimethyltryptamine 7435
Some trade or other names: DMT

(11) Ibogaine 7260
Some trade and other names:
7-Ethyl-6, 6a, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1', 2': 1, 2) azepino 4, 5-b) indole; tabernanthe iboga.

(12) Lysergic acid diethylamide 7315

(13) Marihuana 7360

(14) Mescaline 7381

(15) Peyote 7415
Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or extracts.

(Interprets 21 U.S.C. 812(c), Schedule I(c) (12))

(16) N-ethyl-3-piperidyl benzilate 7482

(17) N-methyl-3-piperidyl benzilate 7484

(18) Psilocybin 7437

(19) Psilocyn 7438

(20) Tetrahydrocannabinols 7370
Synthetic equivalents of the substances contained in plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

_[1] cis or trans tetrahydrocannabinol, and their optical isomers.

_[6] cis or trans tetrahydrocannabinol and their optical isomers.

_[3], [4] cis or trans tetrahydrocannabinol, and its optical isomers.

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.)

(21) Thiophene Analog of Phencyclidine 7470
Some trade or other names:
1-(1-(2-thienyl) cyclohexyl) piperidine); 2-Thienyl Analog of Phencyclidine, TPCP.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Mecloqualone 2572

(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.11; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jun 9, 1977, 8:55 a.m.: Unpublished; filed May 31, 1994, 5:00 p.m.: 17 IR 2335; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-3 Schedule II

Authority: IC 35-48-2-14; IC 35-48-3-1
Affected: IC 35-48-2-6

Sec. 3. (a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the controlled substances code number set forth opposite it.

(b) Substances, vegetable origin, or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding naloxone and its salts and naltrexone and its salts but including the following:

(A) Raw opium 9600
(B) Opium extracts 9610
(C) Opium fluid extracts 9620
(D) Powdered opium 9639
(E) Granulated opium 9640
(F) Tincture of opium 9630
(G) Apomorphine 9030
(H) Codeine 9050
(I) Ethylmorphine 9190
(J) Etorphine hydrochloride 9059
(K) Hydrocodone 9193
(L) Hydromorphone 9194
(M) Metopon 9260
(N) Morphine 9300
(O) Oxycodone 9143
(P) Oxymorphone 9652
(Q) Thebaine 9333

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw (9650).

(4) Coca Leaves (9040) and salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine (9041) or ecgonine (9180).

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy) 9670.

(c) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine 9010
(2) Anileridine 9020
(3) Benzitramide 9800
(4) Dihydrocodeine 9120
(5) Diphenoxylate 9170
(6) Fentanyl 9801
(7) Isomethadone 9226
(8) Levo-alphacetylmethadol 9648
Some trade and other names:
levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM.
(9) Levomethorphan 9210
(10) Levorphanol 9220
(11) Metazocine 9240
(12) Methadone 9250
(13) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-dyphenyl butane 9254
(14) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid9802
(15) Pethidine 9230
(16) Pethidine-Intermediate-A,4-cyano-1- methyl-4-phenylpiperidine 9232
(17) Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate 9233
(18) Pethidine-Intermediate-C,1-methyl-4- phenylpiperidine-4-carboxylic acid 9234
(19) Phenazocine 9715
(20) Piminodine 9730
(21) Racemethorphan9732
(22) Racemorphan 9733

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers 1100

(2) Methamphetamine, including its salts, isomers, and salts of isomers 1105

(3) Phenmetrazine and its salts 1631

(4) Methylphenidate 1724

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Methaqualone 2565
(2) Amobarbital 2125
(3) Secobarbital 2315
(4) Pentobarbital 2270

(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.12; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jun 9, 1977, 8:55 a.m.: Unpublished; filed May 31, 1994, 5:00 p.m.: 17 IR 2336; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-4 Schedule III

Authority: IC 35-48-3-1
Affected: IC 35-48-2-8

Sec. 4. (a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant

effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II, which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or that is the same, except that it contains a lesser quantity of controlled substances 1405

(2) Benzphetamine 1228

(3) Chlorphentermine 1645

(4) Clortermine 1647

(5) Mazindol 1605

(6) Phendimetrazine 1615

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing:

(A) Amobarbital 2125

(B) Secobarbital 2315

(C) Pentobarbital 2270

or any salt thereof and one (1) or more other active medicinal ingredient that are not listed in any schedule.

(2) Any suppository dosage form containing:

(A) Amobarbital 2125

(B) Secobarbital 2315

(C) Pentobarbital 2270

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance that contains any quantity of a derivative of barbituric acid or any salt thereof 2100

(4) Chlorhexadol 2510

(5) Ketamine, its salts, isomers, and salts of isomers 7285

Some other names for ketamine: (-2(2-chlorophenyl) -2-(methylamino) - cyclohexanone

(6) Lysergic acid 7300

(7) Lysergic acid amide 7310

(8) Methyprylon 2575

(9) Sulfondiethylmethane 2600

(10) Sulfonethylmethane 2605

(11) Sulfonmethane 2610

(d) Nalorphine (a narcotic drug) 9400

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than one and eight-tenths (1.8) grams of codeine, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803

(2) Not more than one and eight-tenths (1.8) grams of codeine, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804

(3) Not more than three hundred (300) milligrams of dihydrocodeinone, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium 9805

(4) Not more than three hundred (300) milligrams of dihydrocodeinone, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients, in recognized therapeutic amounts 9806

(5) Not more than one and eight-tenths (1.8) grams of dihydrocodeine, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9807

(6) Not more than three hundred (300) milligrams of ethylmorphine, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808

(7) Not more than five hundred (500) milligrams of opium per one hundred (100) milliliters or per one hundred (100) grams or not more than twenty-five (25) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9809

(8) Not more than fifty (50) milligrams of morphine, per one hundred (100) milliliters or per one hundred (100) grams with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9810

(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of anabolic steroids, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation 4000

(g) For hallucinogenic substances, dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration-approved drug product 7369

(Some other names for dronabinol: (6aR-trans) - 6a, 7, 8, 10a - tetrahydro-6,6,9 - trimethyl - 3-pentyl- 6H - dibenzo[b,d]pyrano-1-ol, or (1) Δ^9 - (trans) - tetrahydrocan-nabinol.) (Indiana Board of Pharmacy; Reg 28, Ch II, Sec 2.13; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jun 9, 1977, 8:55 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-5 Schedule IV

Authority: IC 35-48-3-1

Affected: IC 35-48-2-10

Sec. 5. (a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Barbital 2145

(2) Chloral betaine 2460

(3) Chloral hydrate 2465

(4) Chlordiazepoxide 2744

(5) Clonazepam 2737

(6) Clorazepate 2768

(7) Diazepam 2765

(8) Ethchlorvynol 2540

(9) Ethinamate 2545

(10) Flurazepam 2767

(11) Mebutamate 2800

(12) Meprobamate 2820

(13) Methohexital 2264

(14) Methylphenobarbital 2250

(15) Oxazepam 2835

(16) Paraldehyde 2585

(17) Petrichloral 2591

(18) Phenobarbital 2285

(c) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and

salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Fenfluramine 1670

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion 1608

(2) Phentermine 1640

(3) Pemoline (including organometallic complexes and chelates thereof) 1530

(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.14; filed Jul 9, 1974, 9:29 am: Unpublished; filed Jun 9, 1977, 8:55 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-6 Schedule V

Authority: IC 35-48-3-1

Affected: IC 35-48-2-12

Sec. 6. (a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine, per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine, per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine, per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.15; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-7 Application for exception of stimulant or depression compound; revocation

Authority: IC 35-48-3-1

Affected: IC 35-48-2-1

Sec. 7. Application for exception of a stimulant or depressant compound. (a) Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in Chapter 2, Section 2.13(b) or (c) [856 IAC 2-2-4(b) or (c)] or in Section 2.14 [856 IAC 2-2-5] excepted from the application of all or any part of the Act [IC 35-48] pursuant to IC 1971, 35-24.1-2-8(e) or 10(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, may apply to the Indiana Board of Pharmacy for such exception.

(b) An application for an exception under this section shall be approved by the Board, provided that such application shall contain a copy of the Administration's approval for such request for an exception from the Federal Controlled Substances Act.

(c) Within a reasonable period of time after the receipt of an application for an exception under this section, the Indiana State Board of Pharmacy shall notify the applicant of its acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Indiana State Board of Pharmacy need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section.

(d) The Indiana Board of Pharmacy may at any time revoke any exception granted pursuant to IC 1971, 35-24.1-2-8(e) or 10(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended, upon a finding that such exception from the Federal Controlled Substances Act was terminated, suspended or revoked. The revocation of the exception granted under this Act [IC 35-48] shall become effective upon the Board's notifying the person to whom such exception was granted by certified mail of such revocation. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.21; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-8 Excepted stimulant or depressant compounds

Authority: IC 35-48-3-1

Affected: IC 35-48-2-8; IC 35-48-2-10

Sec. 8. The Indiana Board of Pharmacy may except any compound, mixture, or preparation containing any depressant or stimulant substance listed in Section 2.13(b) or (c) [856 IAC 2-2-4(b) or (c)], or in Section 2.14 [856 IAC 2-2-5] from the application of all or any part of the Act pursuant to IC 1971, 35-24.1-2-8(e) or 10(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, the drugs which were excepted by the Bureau or Administration on April 1, 1973 under section 202(d) of the Federal Controlled Substances Act (21 U.S.C. 812(d)) have been excepted by the Indiana State Board of Pharmacy from the application of IC 1971, 25-24.1-3, 6 and 8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, and the application of Section 3.74(d) [856 IAC 2-3-33(d)] (rule) for administrative purposes only. The excepting of these drugs by the Indiana State Board of Pharmacy should not be construed as an adoption or rejection of the criteria by which these drugs were originally excepted. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exception in order for that drug to be excepted.

The following is a list of the excepted stimulant or depressant compounds under these regulations [856 IAC 2-2]. &BART.**ARTWORK** &COL2.&SIZE.6840PTS. The Excepted Prescription Drugs Table is not on tape. &EART. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.22; filed Jul 9, 1974, 9:29 am: Unpublished; filed Jun 9, 1977, 8:55 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-9 Application for exclusion of stimulant or depression compound; revocation

Authority: IC 35-48-3-1

Affected: IC 35-48-2-1

Sec. 9. Application for exclusion of a stimulant or depressant compound. (a) Any person seeking to have any non-narcotic substance which may, under the Federal Food, Drug, and Cosmetic Act or state law, be lawfully sold over-the-counter without a prescription, excluded from any schedule, pursuant to IC 1971, 35-24.1-2-1(g) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, may apply to the Indiana Board of Pharmacy for such exclusion.

(b) An application for an exclusion under this section shall be approved by the Board, provided that such application shall contain a copy of the Administration's approval for such request for an exclusion from the Federal Controlled Substances Act.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the Indiana State Board of Pharmacy shall notify the applicant of its acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Indiana State Board of Pharmacy need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section.

(d) The Indiana State Board of Pharmacy may at any time revoke any exclusion granted pursuant to IC 1971, 35-24.1-2-1(g) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended, upon a finding that such exclusion from the Federal Controlled Substances Act was terminated, suspended or revoked. The revocation of the exclusion granted under this Act [IC 35-48] shall become effective upon the board's notifying the person to whom such exclusion was granted by certified mail of such revocation. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.23; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-10 Excluded nonnarcotic substances, stimulant or depressant compounds

Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 10. Excluded non-narcotic substances, stimulant, or depressant compounds. (a) The Indiana Board of Pharmacy may exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug and Cosmetic Act or state law, be lawfully sold over-the-counter without a prescription pursuant to IC 1971, 35-24.1-2-1(g) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, the drugs which were excluded by the Bureau or Administration on January 1, 1974 under section 201(g)(1) of the Federal Controlled Substances Act (21 U.S.C. 811(g) (1)) have been excluded by the Indiana State Board of Pharmacy from the schedules of IC 1971, 35-24.1-2-4, 6, 8, 10, and 12 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended. The exclusion of these drugs by the Indiana State Board of Pharmacy should not be construed as an adoption or rejection of the criteria by which these drugs were originally excluded. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exclusion in order for that drug to be excluded. The following is a list of the presently excluded non-narcotic substances under these regulations. &BART.**ARTWORK** &COL2.&SIZE.375PTS. The Excluded Over-the-Counter Drugs Table is not on tape. &EART. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.24; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-11 Exempt chemical preparations

Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 11. Exempt Chemical Preparations. (a) The chemical preparations and mixtures specifically listed in subparagraph (b) of this Section have been exempted by the Indiana Board of Pharmacy from the application of IC 1971, 35-24.1-3-2, 3, 6 and 8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, which preparation or mixture is intended for laboratory, industrial, educational or special research purposes and not for general administration to a human being or other animal. The exemption to be valid must be in strict compliance with the requirements imposed for the preparation or mixture prescribed in Part 1308, Section 1308.24 of Title 21 of the Code of Federal Regulations, effective January 1, 1973, and no exemption granted pursuant to this Section affects the criminal liability for illegal manufacture, distribution, or possession of controlled substances contained in the exempt chemical preparation. Distribution, possession and use of an exempt chemical preparation are lawful for registrants and non-registrants only as long as such distribution, possession or use is intended for laboratory, industrial or educational purposes and not for immediate or subsequent administration to a human being or other animal.

(b) The following preparations and mixtures in the form and quantity listed in the application submitted (indicated as the “date of application”) are designated as exempt chemical preparations for the purposes set forth in this Section. &BART.**ARTWORK** &COL2.&SIZE.9965PTS. The Exempt Chemical Preparations Table is not on tape. &EART. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.25; filed Jul 9, 1974, 9:29 am: Unpublished; filed Jun 9, 1977, 8:55 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-12 Rulemaking hearings

Authority: IC 35-48-3-1
Affected: IC 4-22-2; IC 35-48-3-1

Sec. 12. Hearings for rule making. In any case where the Indiana Board of Pharmacy shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to IC 1971, 35-24.1-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, the procedures for such hearing and accompanying proceedings shall be governed generally by the rule making procedures set forth in IC 1971, 4-22-2 as amended, and such procedures, if relating to standards and schedules, be of record in accordance with IC 1971, 35-24.1-2-1 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.31; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-13 Purpose of public hearings

Authority: IC 35-48-3-1
Affected: IC 35-48-3-1

Sec. 13. Purpose of hearing. Whenever proceedings are initiated pursuant to IC 1971, 35-24.1-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, of this chapter, the Indiana Board of Pharmacy shall hold a hearing of record for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to IC 1971, 35-24.1-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

On the date set for hearing any interested party in person or by attorney shall be afforded an adequate opportunity to participate in the formulation of the proposed rule or rules through the presentation of facts or argument or the submission of written data or views. All relevant matter presented shall be given full consideration by the Board.

The Board may adopt procedures in addition to those required by this Act [IC 35-48] including the holding of conferences and inviting and permitting the submission of suggestions, facts, argument and views of interested persons in advance of the drafting of the proposed rule or rules. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.32; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-14 Exempt anabolic steroid products

Authority: IC 35-48-2-14
Affected: IC 35-48-2

Sec. 14. The following anabolic steroid containing compounds, mixtures, or preparations have been exempted from this rule and are not controlled substances:

Trade Name	Composition	Company
Androgyn L.A.	Vial; testosterone nathate 90 mg-ml; estradiol valerate 4 mg-ml	Forest Pharmaceuticals St. Louis, MO
Andro-estro 90-4	Vial; testosterone enanthate 90 mg-ml; estradiol valerate 4 mg-ml	Rugby Laboratories Rockville Centra, NY
depANDROGYN	Vial; testosterone cypionate 50 mg-ml;estradiol cypionate 2 mg-ml	Forest Pharmaceuticals St. Louis, MO
DEPO-T.E.	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Quality Researchuticals Carmel, IN
deptestROGEN	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Martica Pharmaceuticals Phoenix, AZ
Duomone	Vial; testosterone enanthate 90 mg-ml; estradiol valerate 4 mg-ml	Wintec Pharmaceuticals Pacific, MO
DURAtestRIN	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	W.E. Hauck Alpharetta, GA
DUO-SPAN II	Vial; testosterone cypionate 50 mg-ml; Esterified cypionate 2 mg-ml	Primedics Laboratories Gardena, CA
Estratest	Tablet; esterified estrogens 1.25 mg; methyltestosterone 2.5 mg	Solvay Pharmaceuticals Marietta, GA
Estratest HS	Tablet; esterified estrogens 0.625 mg; methyltestosterone 1.25 mg	Solvay Pharmaceuticals
PAN estra test	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Pan American Labs Covington, LA
Premarin with methyltestosteron	Tablet; conjugated estrogens 1.25 mg; methyltestosterone 10.0 mg	Ayerst Labs, Inc. New York, NY
Premarin with methyltestosteron	Tablet; conjugated estrogens 0.625 mg; methyltestosterone 5.0 mg	Ayerst Labs, Inc. New York, NY
Test-ESTRO cypi	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Rugby Laboratories Rockville Center, NY
Testosterone Cyp estradiol Cyp 2	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	I.D.E. - Interstate Amityville, NY
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Best Generics No. Miami Beach, FL
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Goldline Labs Ft. Lauderdale, FL
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Scein Pharmaceuticals Port Washington, NY
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Steris Labs, Inc. Phoenix, AZ
Testosterone tion	Vial; testosterone enanthate 90 mg-ml; estradiol valerate 4 mg-ml	Steris Labs, Inc. Phoenix, AZ

(Indiana Board of Pharmacy; 856 IAC 2-2-14; filed May 31, 1994, 5:00 p.m.: 17 IR 2337; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 3. Registration Information Special Instructions

856 IAC 2-3-1 Registration information furnished upon request

Authority: IC 35-48-3-1

Affected: IC 35-48-3-1

Sec. 1. Information; special instructions. Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Indiana State Board of Pharmacy. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.02; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-2 Persons required to register

Authority: IC 35-48-3-1

Affected: IC 35-48-3-3

Sec. 2. Persons required to register. Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance shall obtain annually a registration unless exempted by law or pursuant to sections 3.14 3.17 [856 IAC 2-3-5 856 IAC 2-3-8] of this chapter. Only persons actually engaged in such activities are required to obtain registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration).

As soon after the effective date of these rules as is practicable, the Board shall issue a provisional certificate to all persons when in possession of a valid State of Indiana or Federal certificate of registration authorizing such persons to manufacture, distribute, dispense, prescribe or possess controlled substances. The provisional certificates shall be valid until the Board shall declare that applications for annual renewals shall begin and until such applications have been acted upon by the Board. During the first renewal period, when it is instituted, applications shall be required from all prospective registrants in alphabetically ordered increments according to a schedule to be adopted by the Board. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.11; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-3 Independent activities; separate registration required; exceptions

Authority: IC 35-48-3-1

Affected: IC 35-48-3-3; IC 35-48-3-4

Sec. 3. Separate registration for independent activities. (a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing controlled substances listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6];

(4) Conducting research (other than research described in sub-paragraph (6) of this paragraph) with controlled substances listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6];

(5) Conducting instructional activities with controlled substances listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6];

(6) Conducting research with narcotic drugs listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6] for the purpose of continuing the dependence on such drugs of a narcotic drug dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program pursuant to a Notice of Claimed Investigational Exemption for a New Drug approved by the Food and Drug Administration;

(7) Conducting research and instructional activities with controlled substances listed in Schedule I [856 IAC 2-2-2]; and

(8) Conducting chemical analysis with controlled substances listed in any Schedule.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture;

(2) A person registered to manufacture any controlled substance listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6] shall be authorized to conduct chemical analysis and pre-clinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in Schedule I [856 IAC 2-2-2] shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in a research protocol federally approved by the Drug Enforcement Administration and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to section 3.16 [856 IAC 2-3-7], and to conduct instructional activities with controlled substances; and

(5) A person registered or authorized to conduct research (other than research described in paragraph (a)(6) of this section) with controlled substances listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6] shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to distribute such substances to other persons registered or authorized to conduct chemical analysis, exempted from registration pursuant to Section 3.16 [856 IAC 2-3-7], and to conduct instructional activities with controlled substances;

(6) A person registered to dispense controlled substances listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6] shall be authorized to conduct research (other than research described in paragraph (a) (6) of this section) and to conduct instructional activities with those substances.

(7) A person registered as a manufacturer shall be authorized to conduct one, all or several of the activities and coincident activities enumerated and described in paragraphs (b)(1), (b)(2), (b)(3), (b)(4), and (b)(5) under a single registration if set forth in his application and pertaining to those controlled substances or schedules as set forth in his application. (For example, a manufacturer under a single registration may perform all or any of the following activities, by way of illustration and not limitation; (a) manufacture and distribute any controlled substance or basic class, (b) chemical analysis, (c) Schedule I [856 IAC 2-2-2] research pursuant to a federally approved protocol, (d) Schedule II through V [856 IAC 2-2-3 856 IAC 2-2-6] research, and (e) instructional activity if set forth in his application and for those controlled substances or schedules as set forth for each activity.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I [856 IAC 2-2-2] may conduct research with any substance listed in Schedule I [856 IAC 2-2-2] for which he has filed and had approved a research protocol, by the Federal Drug Enforcement Administration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.12; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-4 Separate registrations for separate locations; exceptions

Authority: IC 35-48-3-1

Affected: IC 16-1-39-2; IC 16-1-40; IC 35-48

Sec. 4. Separate registrations for separate locations. (a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, dispensed, or possessed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of IC 1971, 35-24.1-3-2(c)(2) [Repealed by P.L.26-1977, SECTION 25. Compare IC 35-48-3-3.] as amended.

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

(c) The requirement of registration is waived for ambulances as defined by IC 16-1-39-2 and 836 IAC 1-1-1 operated by an ambulance service provider also defined at 836 IAC 1-1-1 which holds certification as a provider organization as this term is defined in IC 16-1-40 from the Indiana Emergency Medical Services Commission, providing that the pharmacies of the supervising or sponsoring hospitals hold a valid Indiana Board of Pharmacy permit and valid Indiana and Federal Controlled Substances Registration. (Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.13; filed Jul 9, 1974, 9:29 am: unpublished; filed Feb 11, 1981, 9:05 am: 4 IR 377; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-5 Exemption of agents or employees; affiliated practitioners; paramedics

Authority: IC 35-48-3-1

Affected: IC 16-1-40; IC 35-48-3-3

Sec. 5. Exemption of agents and employees; affiliated practitioners. (a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment.

(b) An individual practitioner (other than an intern, resident, or foreign-trained physician) who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his employment, administer, and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he practices, under the registration of the employer or principal practitioner in lieu of being registered himself. (For example, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances in a pharmacy if so registered).

(c) An individual practitioner who is an intern, resident, or foreign-trained physician may dispense, administer, and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom he is employed in lieu of being registered himself, provided that:

(1) Such dispensing or prescribing is done in the usual course of his professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he is practicing;

(3) The hospital or other institution by whom he is employed has determined that the individual practitioner is so permitted to dispense, administer, or prescribe drugs by the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his employment with the hospital or institution;

(5) The hospital or other institution authorizes the intern, resident, or foreign-trained physician to dispense or prescribe under the hospital registration and designates a specific internal code number for each intern, resident, or foreign-trained physician so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., AP 0123456-10 or AP 0123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioner is kept by the hospital or other institution and is made available to the public upon request for the purpose of verifying the authority of the prescribing individual practitioner.

(d) The requirement of registration is waived for advanced emergency medical technicians and emergency paramedics as described in IC 16-1-40 and 836 IAC 2-1-1 insofar as they administer controlled substances within the applicable requirements and standards of IC 16-1-40 as well as the rules and regulations promulgated thereunder by the Indiana Emergency Medical Services Commission. (Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.14; filed Jul 9, 1974, 9:29 am: unpublished; filed Feb 11, 1981, 9:05 am: 4 IR 378; errata, 4 IR 536; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-6 Exemption of military or public health service personnel

Authority: IC 35-48-3-1

Affected: IC 35-48-3-3

Sec. 6. Exemption of certain military and other personnel. (a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his official duties. Such officials shall follow procedures set forth in Part 6 [856 IAC 2-6] of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his Social Security identification number.

(b) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.15; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-7 Exemption of law enforcement officers; registration of law enforcement laboratories

Authority: IC 35-48-3-1

Affected: IC 35-48-3-3

Sec. 7. Exemption of law enforcement officials. (a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Drug Enforcement Administration, any officer of the U.S. Bureau of Customs, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of his official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his official duties.

(c) Any official exempted by this section may procure any controlled substance in the course of an inspection, in accordance with IC 1971, 35-24.1-5-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, or in the course of any criminal investigation involving the person from whom the substance was procured.

(d) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories must obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in IC 1971, 35-24.1-5-6(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. For the purpose of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.16; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-8 Exemption of civil defense officials

Authority: IC 35-48-3-1

Affected: IC 35-48-3-3

Sec. 8. Exemption of civil defense officials. (a) The requirement of registration is waived for any offical of a civil defense or disaster relief organization who, in the course of his official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is from the U.S. General Services Administration and in accordance with the rules of the U.S. Office of Emergency Preparedness.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization during a state of emergency or disaster within his jurisdiction proclaimed by the President or by a concurrent resolution of the Congress, which official, in the course of his official duties during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances, provided that all such procurement is on a special “Civil Defense Emergency Order Form,” as described in this section.

(c) Civil Defense Emergency Order Forms shall be furnished by the U.S. Office of Emergency Preparedness and will contain the name of the civil defense or disaster relief organization. Such forms may be used and are valid only during a state of emergency or disaster proclaimed by the President or by a concurrent resolution of the Congress for the area in which the organization using such forms has civil defense or disaster relief jurisdiction, who shall state his position and the nature and legal designation of the emergency or disaster. Such forms may be filled by any person registered under the Act [IC 35-48]. The Organization shall, upon the execution of a Civil Defense Emergency Order Form, be deemed to be registered under the Act [IC 35-48] for purposes or recordkeeping pursuant to Part 4 [856 IAC 2-4].

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.17; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-9 Registration fees
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 9. (a) For each registration or reregistration to manufacture controlled substances, the registrant shall pay a fee of one hundred dollars ($100).

(b) For each registration or reregistration to distribute controlled substances, the registrant shall pay a fee of one hundred dollars ($100).

(c) For each registration or reregistration to dispense or to conduct research or instructional activities with controlled substances listed in 856 IAC 2-2-3 through 856 IAC 2-2-6, the registrant shall pay a fee of one hundred dollars ($100).

(d) For each registration or reregistration to conduct research or instructional activities with controlled substances listed in 856 IAC 2-2-2, the registrant shall pay a fee of one hundred dollars ($100).

(e) For each registration or reregistration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of one hundred dollars ($100).

(f) For each registration or reregistration for a practitioner seeking to prescribe, administer, or dispense controlled substances, the registrant shall pay a fee of sixty dollars ($60). (Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.21; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jul 8, 1981, 9:00 a.m.: 4 IR 1499; filed Jul 20, 1984, 10:00 a.m.: 7 IR 2379; filed Aug 21, 1986, 10:30 a.m.: 10 IR 63; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3106; readopted filed Oct 17, 2001, 3:25 p.m.: 25 IR 940)

856 IAC 2-3-10 Time and method of payment; refund (Repealed)

Sec. 10. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-3-11 Persons exempt from fee
Authority: IC 35-48-3-1
Affected: IC 35-48-3-1

Sec. 11. Persons exempt from fee. (a) The Indiana State Board of Pharmacy shall exempt from payment of a fee for registration or re-registration the following persons:

(1) Any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who or which is authorized to procure or purchase controlled substances for official use; and

(2) Any official, employee, or other civil officer or agency of the United States, or any State, or any political subdivision or agency thereof, who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any combination thereof, in the course of his or its official duties or employment.

(b) In order to claim exemption from payment of a registration or re-registration fee, the registrant shall have completed the certification on the appropriate form, wherein the registrant's superior (if an individual) or officer (if an agency) certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or handle controlled substances.

(c) Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirements or duties prescribed by law. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.23; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-12 Time for registration or re-registration application
Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 12. Time for application for registration; expiration date. (a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted by the Indiana Board of Pharmacy.

(b) Any person who is registered may apply to be re-registered not more than 60 days, before the expiration date his registration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.31; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-13 Application forms; reregistration forms
Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 13. (a) If any person is required to be registered, and is not so registered and is applying for registration, the following apply:

(1) To manufacture and perform other coincident activities (see 856 IAC 2-3-3(b)(7) [section 3(b)(7) of this rule]) with controlled substances, he or she shall apply on Form CSR-1A.

(2) To dispense, or to conduct research (other than research described in 856 IAC 2-3-3(a)(6) [section 3(a)(6) of this rule]) with, or to conduct instructional activities with, controlled substances listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, he or she shall apply on Form CSR-1.

(3) To conduct research with narcotic drugs listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, as described in 856 IAC 2-3-3(a)(6) [section 3(a)(6) of this rule], he or she shall apply on Form CSR-1.

(4) To conduct research with controlled substances listed in Schedule I under 856 IAC 2-2-2, he or she shall apply on Form CSR-1 in accordance with an approved Schedule I under 856 IAC 2-2-2 research protocol. Such protocol shall be subject to inspection by the Indiana board of pharmacy.

(5) To conduct instructional activities with controlled substances listed in Schedule I under 856 IAC 2-2-2, he or she shall apply as a researcher on Form CSR-1 with two (2) copies of a statement describing the nature, extent, and duration of such instructional activities attached to the form.

(6) To conduct chemical analysis with controlled substances listed in any schedule, he or she shall apply on Form CSR-1.

(7) To distribute controlled substances, he or she shall apply on Form CSR-1.

(b) If any person is registered and is applying for reregistration, the following apply:

(1) To manufacture and perform other coincident activities (see 856 IAC 2-3-3(b)(7)[section 3(b)(7) of this rule]), with controlled substances, he or she shall apply on Form CSRII-A.

(2) To dispense, or to conduct research (other than research described in 856 IAC 2-3-3(a)(6)[section 3(a)(6) of this rule]) with, or to conduct instructional activities with, controlled substances listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, he or she shall apply on Form CSR-II.

(3) To conduct research with narcotic drugs listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, as described in 856 IAC 2-3-3(a)(6) [section 3(a)(6) of this rule], he or she shall apply on Form CSR-II.

(4) To continue to conduct research with controlled substances listed in Schedule I under 856 IAC 2-2-2 under one (1) or

more approved research protocols, by the Drug Enforcement Administration, he or she shall apply on Form CSR-II.

(5) To continue to conduct instructional activities with controlled substances listed in Schedule I under 856 IAC 2-2-2 under one (1) or more approved instructional statements, he or she shall apply as a researcher on Form CSR-II.

(6) To conduct chemical analysis with controlled substances listed in any schedule, he or she shall apply on Form CSR-II.

(7) To distribute controlled substances, he or she shall apply on Form CSR-II.

(c) Applications for registration may be obtained by writing to the controlled substance division of the Indiana board of pharmacy. Applications for reregistration will be mailed, as applicable, to each registered person approximately sixty (60) days before the expiration date of his or her registration; if any registered person does not receive such forms within forty-five (45) days before the expiration date of his or her registration, he or she must promptly give notice of such fact and request such forms by writing to the controlled substance division of the Indiana board of pharmacy.

(d) Each application for registration to handle any basic class of controlled substance listed in Schedule I under 856 IAC 2-2-2 (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II under 856 IAC 2-2-3, or to conduct research with any narcotic controlled substance listed in Schedule II under 856 IAC 2-2-3, shall include the controlled substances code number, as set forth in Part I [856 IAC 2-1], for each basic class or substance to be covered by such registration.

(e) Each application shall include all information called for on the form unless the item is not applicable, in which case this fact shall be indicated.

(f) Each application, attachment, or other document filed as part of an application shall be signed by:

(1) the applicant, if an individual;

(2) a partner of the applicant, if a partnership; or

(3) an officer or authorized representative of the applicant, if a corporation, corporate division, association, trust, or other entity.

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.32; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1342)

856 IAC 2-3-14 Filing of application; joint filing (Repealed)

Sec. 14. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-3-15 Acceptance for filing; defective applications; requests for additional information (Repealed)

Sec. 15. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-3-16 Additional information; failure to supply

Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 16. Additional information. The Indiana State Board of Pharmacy may require an applicant to submit such documents or written statements of fact relevant to the application as the Board deems necessary and as provided by IC 1971, 35-24.1-3-3(a) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable period of time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Indiana State Board of Pharmacy in granting or denying the application. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.35; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-17 Amendment or withdrawal of application

Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 17. Amendments to and withdrawal of applications. An application may be amended or withdrawn without permission of the Indiana Board of Pharmacy at any time. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.36; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-18 Inspection and review of application by board

Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 18. Administrative review generally. The Indiana Board of Pharmacy may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to IC 1971, 35-24.1-5-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. The Indiana Board of Pharmacy shall review the application for registration and other information regarding an applicant in order to determine whether the applicable standards of IC 1971, 35-24.1-3 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, have been met by the applicant. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.41; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-19 Certificate of registration; denial of registration

Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 19. Certificate of registration; denial of registration. (a) The Indiana State Board of Pharmacy shall issue a Certificate of Registration Form CSR-3 to an applicant if the issuance of registration or re-registration is required under the applicable provisions of IC 1971, 35-24.1-3 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. In the event that the issuance of registration or re-registration is not required, the Indiana State Board of Pharmacy may deny the application. Before denying any application, the Indiana State Board of Pharmacy shall issue an order to show cause pursuant to Section 3.46 [856 IAC 2-3-23] and, if requested by the applicant, shall hold a hearing on the application pursuant to Section 3.51, through Section 3.53 [856 IAC 2-3-24 856 IAC 2-3-26].

(b) The Certificate of Registration shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Controlled Substances Code Number (as set forth in Part 2 [856 IAC 2-2] of this Act) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the Certificate of Registration in a readily retrievable manner and shall permit inspection of the Certificate of Registration and shall permit inspection of the certificate by any official, agent, or employee of the Board or any agency engaged in enforcement of laws relating to controlled substances. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.42; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-20 Suspension or revocation of registration

Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 20. Suspension or revocation of registration. (a) The Indiana Board of Pharmacy may suspend any registration pursuant to IC 1971, 35-24.1-3-4 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, for any period of time he determines.

(b) The Indiana Board of Pharmacy may revoke any registration pursuant to IC 1971, 35-24.1-3-4 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(c) Before revoking or suspending any registration, the Indiana Board of Pharmacy shall issue an order to show cause, such order shall be sent by certified mail to address of the registrant, advising registrant of his rights to a hearing, Form CSR-4, pursuant to section 3.46 [856 IAC 2-3-23]. Notwithstanding the requirements of this section, however, the Indiana Board of Pharmacy may suspend any registration pending a final order pursuant to section 3.44 [856 IAC 2-3-21].

(d) Upon service of the final order of the Indiana Board of Pharmacy following a hearing or waiver thereof suspending or revoking registration, the registrant shall immediately deliver his Certificate of Registration to the Indiana Board of Pharmacy. Also, upon service of the final order of the Indiana Board of Pharmacy suspending or revoking registration, the registrant shall, as instructed by the Indiana Board of Pharmacy:

(1) Deliver all controlled substances in his possession to the Indiana Board of Pharmacy or to authorized agents of the Indiana Board of Pharmacy; or

(2) Place all controlled substances in his possession under seal as described in IC 1971, 35-24.1-3-4(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration to the Indiana Board of Pharmacy. Also, the registrant shall, as instructed by the Indiana Board of Pharmacy:

(1) Deliver to the Indiana Board of Pharmacy or to authorized agents of the Indiana Board of Pharmacy all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession; or

(2) Place all of such substances under seal as described in IC 1971, 35-24.1-3-4(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.43; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-21 Suspension pending final order

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 21. Suspension of registration pending final order. (a) The Indiana Board of Pharmacy may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where it finds that there is an imminent danger to the public health or safety. If the Indiana Board of Pharmacy so suspends, it shall serve with the order to show cause pursuant to section 3.46 [856 IAC 2-3-23] an order of immediate suspension which shall contain a statement of its findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration to the Indiana Board of Pharmacy. Also, upon service of the order of the Indiana Board of Pharmacy immediately suspending registration, the registrant shall, as instructed by the Indiana Board of Pharmacy:

(1) Deliver all affected controlled substances in his possession to the Indiana Board of Pharmacy or to authorized agents of the Indiana Board of Pharmacy; or

(2) Place all of such substances under seal as described in IC 1971, 35-24.1-3-4(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(c) Any suspension shall continue in effect until the conclusion of all preceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Indiana Board of Pharmacy or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to section 3.46 [856 IAC 2-3-23], which request shall be granted by the Indiana Board of Pharmacy who shall fix a date for such hearing as early as reasonably possible. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.44; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-22 Extension of registration pending re-registration order

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 22. Extension of registration pending final order. In the event that an applicant for re-registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for re-registration at least 30 days before the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Indiana Board of Pharmacy so issues its final order. The Indiana Board of Pharmacy may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for re-registration at least 30 days before expiration of the existing registration, with or without request by the registrant, if the Indiana Board of Pharmacy finds that such extension is not inconsistent with the public health and safety. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.45; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-23 Order to show cause

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 23. Order to show cause. (a) If, upon examination of the application for registration from any applicant and other information regarding the applicant, the Indiana Board of Pharmacy is unable to make the determinations required by the applicable provisions of IC 1971, 35-24.1-3-3 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended, to register the applicant, the Indiana Board of Pharmacy shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information regarding any registrant, the Indiana Board of Pharmacy determines that the registration of such registrant is subject to suspension or revocation pursuant to IC 1971, 35-24.1-3-4 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended, the Indiana Board of Pharmacy shall serve upon the registrant an order to show cause why a registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Indiana Board of Pharmacy at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) The Indiana Board of Pharmacy shall hold a hearing at the time and place stated in the order, pursuant to section 3.51 [856 IAC 2-3-24].

(e) When authorized by the section 3.51 [856 IAC 2-3-24] any agent of the Indiana Board of Pharmacy may serve the order to show cause. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.46; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-24 Evidentiary hearing
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 24. The controlled substances advisory committee shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.51; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)

856 IAC 2-3-25 Hearing procedures
Authority: IC 35-48-3-1
Affected: IC 4-21.5; IC 35-48-3-6

Sec. 25. Hearing for granting, denial, revocation, or suspension of application. (a) In any case where the advisory committee shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures of IC 1971, 4-22-1-1 to 4-22-1-30 [Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.], as amended, and by sections 3.52-3.53 [this section and 856 IAC 2-3-26].

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act [IC 35-48] or any other law of this State.

(c) At any such hearing the advisory committee shall designate one of its members as presiding officer.

(d) At any such hearing a quorum of the advisory committee consisting of a majority of its membership shall hear the evidence and the disputed issues of law and they shall after the conclusion of the hearing, prepare for the Board recommended findings, facts, and conclusions of law.

(e) The committee's recommended findings and facts and conclusions of law shall be acted on by the Board in the manner required by IC 1971, 4-22-1 [Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.]. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.52; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-26 Modification or waiver of rules
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 26. Waiver or modification of rules.The presiding officer at the advisory committee hearings or of the Indiana Board of Pharmacy (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines than no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served and if all parties consent. Such notice of modification or waiver shall be made a part of the record of the hearing. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.53; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-27 Modification of registration
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 27. Modification in registration. Any registrant may apply to modify his registration to authorize the handling of additional controlled substances or to change his name or address by submitting a letter of request to the Indiana Board of Pharmacy. The letter shall contain the registrant's name, address, registration number, and the substances and/or schedule to be added to his registration or the name or address and shall be signed by the same person who signed the most recent application for registration or re-registration. If the registrant is seeking to handle additional controlled substances listed in Schedule I [856 IAC 2-2-2] for the purpose of research or instructional activities, a Federally approved research protocol describing each research project involving the additional substances shall be subject to inspection by the Indiana Board of Pharmacy or he shall attach two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration.

If the modification of registration is approved, the Indiana Board of Pharmacy shall issue a new certificate of registration to the registrant, who shall maintain it with the old certificate of registration until the expiration date. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.61; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-28 Termination of registration; notice to board
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 28. Termination of registration. The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Indiana Board of Pharmacy promptly of such fact. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.62; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-29 Transfer of registration
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 29. Transfer of registration. No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Indiana Board of Pharmacy may specifically designate and then only pursuant to its written consent. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.63; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-30 Security requirements; approval of security system
Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 30. Security requirements generally. (a) All applicants and registrants shall provide and maintain effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Indiana Board of Pharmacy shall use the security requirements set forth in Sections 3.72-3.76 [856 IAC 2-3-31 856 IAC 2-3-35] as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Sections 3.72 [856 IAC 2-3-31], 3.73 [856 IAC 2-3-32], and 3.75 [856 IAC 2-3-34] may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in Sections 3.72-3.76 [856 IAC 2-3-31 856 IAC 2-3-35] may be deemed

sufficient by the Indiana Board of Pharmacy after evaluation of the overall security system and needs of a registrant or applicant. In evaluating the overall security system of a registrant or applicant, the Indiana Board of Pharmacy may consider any of the following factors as it may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units usable powders or nonusable powders);

(3) The quantity of controlled substance handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in Sections 3.72-3.76 [856 IAC 2-3-31 856 IAC 2-3-35] when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in Sections 3.72-3.76 [856 IAC 2-3-31 856 IAC 2-3-35] may submit any plans, blueprints, sketches or other materials regarding the proposed security system to the Indiana Board of Pharmacy.

(e) Approval by the Drug Enforcement Administration of any security system, proposed security system, plans, blueprints, sketches or other material as being in substantial compliance with the requirements as set forth in 301.72-301.76 of Title 21 of the Code of Federal Regulations shall be deemed in compliance with Sections 3.71 through 3.75 [856 IAC 2-3-30 856 IAC 2-3-34] of these regulations, where applicable.

(f) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 20, 1971, shall be deemed to comply substantially with the standards set forth in Sections 3.71 [this section], 3.72 [856 IAC 2-3-31], 3.73 [856 IAC 2-3-32], and 3.75 [856 IAC 2-3-34]. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.71; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-31 Storage areas; security controls for nonpractitioners

Authority: IC 35-48-3-1

Affected: IC 35-48-3-7

Sec. 31. Physical security controls for nonpractitioners: Storage Areas. (a) Schedules I and II [856 IAC 2-2-2 and 856 IAC 2-2-3]. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II [856 IAC 2-2-2 or 856 IAC 2-2-3] shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet.

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques.

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Indiana Board of Pharmacy or the Drug Enforcement Administration may approve.

(2) A vault constructed before, or under construction on October 1, 1973, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after October 1, 1973:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent; 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond or a 24-hour control station operated by the registrant or such other protection as the Indiana Board of Pharmacy or the Drug Enforcement Administration may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Indiana Board of Pharmacy or the Drug Enforcement Administration.

(b) Schedules III, IV, and V [856 IAC 2-2-4 856 IAC 2-2-6]. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules

III, IV, and V [856 IAC 2-2-4 856 IAC 2-2-6] shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe which complies with the requirements set forth in paragraph (a)(1) of this section;

(2) A vault which complies with the requirements set forth in either paragraph (a)(2) or (3) of this section or

(3) A building or area located within a building, which building or area:

(i) Has walls or perimeter fences of sufficient height and construction to provide security from burglary;

(ii) Has substantial doors which may be securely locked during non-working hours by a multiple-position combination or key lock;

(iii) Is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond or a 24-hour control station operated by the registrant or such other protection as the Indiana Board of Pharmacy or the Drug Enforcement Administration may approve; and

(iv) In which all controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.

(c) Multiple storage areas. Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

(e) Compliance with the requirements prescribed in Part 301, Section 301.72 of Title 21 of the Code of Federal Regulations, effective April 1, 1973, shall be deemed in compliance with this section. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.72; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-32 Manufacturing areas; security controls for nonpractitioners

Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 32. Physical security controls for nonpractitioners: Manufacturing areas. All manufacturing activities (including processing, packaging, and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or a local or State Police agency which has a legal duty to respond, or a 24-hour control station operated by registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. “Limited access” may be provided in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: Provided: that he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

(d) Compliance with the requirements prescribed in Part 301, Section 301.73 of Title 21 of the Code of Federal Regulations, effective April 1, 1973, shall be deemed in compliance with this section.

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.73; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-33 Additional security controls for nonpractitioners

Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 33. Other security controls for nonpractitioners: (a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance the registrant shall make a good faith inquiry either with the Indiana Board of Pharmacy or with the D.E.A. to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Indiana Board of Pharmacy of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify in writing the Indiana Board of Pharmacy of any theft or significant loss of any controlled substances upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V [856 IAC 2-2-3 856 IAC 2-2-6] as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address and state and federal registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Part 3.5 [856 IAC 2-3-24 856 IAC 2-3-26] hereof shall be complied with for any distribution of a controlled substance listed in Schedule II [856 IAC 2-2-3]. For purposes of this paragraph, the term “customer” includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in Section 3.72 [856 IAC 2-3-31]. In addition, the registrant shall employ precautions (e.g., assuring that shipping

containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.74; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-34 Storage; security controls for practitioners

Authority: IC 35-48-3-1

Affected: IC 35-48-3-7

Sec. 34. Physical security controls for practitioners. (a) Controlled substances listed in Schedule I [856 IAC 2-2-2] shall be stored in a securely locked substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V [856 IAC 2-2-3 856 IAC 2-2-6] shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners (as defined) in Chapter I, 1.01 [856 IAC 2-1-1] may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

Controlled substances (institutional practitioners ward and floor stock) listed in Schedule II [856 IAC 2-2-3] and narcotic drugs in Schedule III [856 IAC 2-2-4] shall be stored in a securely locked substantially constructed cabinet or device. Controlled substances (institutional practitioners ward and floor stock) listed in Schedules III, IV, and V [856 IAC 2-2-4 856 IAC 2-2-6] may be dispersed in their ward or floor stock in such a manner as to obstruct theft or diversion of these controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.75; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-35 Additional security controls for practitioners

Authority: IC 35-48-3-1

Affected: IC 35-48-3-7

Sec. 35. Other security controls for practitioners. (a) The registrant shall not employ as an agent or employee who has access to controlled substances any person who has had an application for registration denied, or has had his registration revoked, or has been convicted of a violation of State or Federal law relative to the manufacture, distribution, dispensing or possession of controlled substances.

(b) The registrant shall notify the Indiana Board of Pharmacy of the theft or significant loss of any controlled substances upon discovery of such loss or theft. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.76; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 4. Records and Inventories of Registrants

856 IAC 2-4-1 Records and inventories

Authority: IC 35-48-3-1

Affected: IC 35-48-3-7

Sec. 1. (a) Every registrant shall keep records and maintain inventories in conformance with the record keeping and inventorying requirements of federal law and regulation.

(b) For purposes of this section, "readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, red-lined, or in some manner visually identifiable apart from other items appearing on the records. Manufacturers, distributors, and research records or electronic data processing printouts shall be made available within five (5) working days after a request by the Indiana board of pharmacy for such records or information on controlled substances transactions.

(c) Each registered pharmacy shall maintain, for a period of two (2) years, its prescriptions of controlled substances by maintaining any of the following:

(1) Three (3) separate files as follows:

(A) A file for Schedule II drugs dispensed.

(B) A file for Schedules III, IV, and V drugs dispensed.

(C) A file for prescriptions for all other drugs dispensed.

(2) Two (2) separate files as follows:

(A) A file for all noncontrolled drugs dispensed.

(B) Another file for all controlled drugs dispensed in Schedules II, III, IV, and V. If this method is used, the prescriptions in the file for Schedules III, IV, and V must be stamped with the letter "C" in red ink, not less than one (1) inch high, in the lower right-hand corner.

(3) Two (2) separate files as follows:

(A) A file for Schedule II drugs dispensed.

(B) Another file for Schedules III, IV, and V drugs, including all other noncontrolled drugs dispensed. If this method is used, the prescriptions in the file of Schedules III, IV, and V drugs must be stamped with the letter "C" in red ink, not less than one (1) inch high, in the lower right-hand corner.

However, if a pharmacy employs an automated data processing system or other electronic record keeping system for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" under subdivisions (2) and (3) is waived. (Indiana Board of Pharmacy; Reg 28, Ch IV, Sec 4.01; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2504; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 5. Order Forms

856 IAC 2-5-1 Order form requirements

Authority: IC 35-48-3-1

Affected: IC 35-48-3-8

Sec. 1. Order Form Requirements Generally. Compliance with the requirements prescribed in section 308 of the Federal Controlled Substances Act (21 U.S.C. 828), and in Part 305 of Title 21 of the Code of Federal Regulations, effective April 1, 1973 shall be deemed compliance with the requirements of IC 1971, 35-24.1-3-7 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. (Indiana Board of Pharmacy; Reg 28,Ch V,Sec 5.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 6. Issuance, Filling and Filing Prescriptions

856 IAC 2-6-1 Scope of rules governing prescriptions

Authority: IC 35-48-3-1

Affected: IC 35-48-3-9

Sec. 1. Scope of Part 6. Rules governing the issuance, filling and filing of prescriptions pursuant to IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, are set forth generally in that section and specifically by the sections of this part [856 IAC 2]. (Indiana Board of

Pharmacy; Reg 28,Ch VI,Sec 6.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-2 Persons entitled to issue prescriptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 2. (a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances by the state; and

(2) either registered or exempted from registration pursuant to 856 IAC 2-3-5(b) or 856 IAC 2-3-6.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an individual practitioner or a practitioner's authorized agent.

(c) Controlled substances prescriptions issued by individual practitioners in adjoining states to Indiana or other states are considered valid prescriptions if the practitioner issuing the prescription has a current and valid Drug Enforcement Administration certificate registration number. It is the pharmacist's responsibility as with all controlled substances prescriptions, to be sure beyond reasonable doubt in his or her professional judgment that the practitioner is issuing the prescription in good faith and has a valid Drug Enforcement Administration certificate of registration. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.02; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)

856 IAC 2-6-3 Purpose of prescription; prohibitions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 3. Purpose of issue of prescription. (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose in a reasonable quantity by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription, within the meaning and intent of IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.03; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-4 Issuance of prescriptions; information required
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 4. Manner of issuance of prescriptions. (a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and Federal Controlled Substance registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

(b) An intern, resident, or foreign-trained physician exempted from registration under section 3.14(c) [856 IAC 2-3-5(c)], shall include on all prescriptions issued by him the Federal Controlled Substance registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in section 3.14(c) [856 IAC 2-3-5(c)], in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, or foreign-trained physician stamped or printed on it, as well as the signature of the physician.

(c) An official exempted from registration under section 3.15 [856 IAC 2-3-6] shall include on all prescriptions issued by him, his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the Federal Controlled Substance registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or hand-printed on it, as well as the signature of the officer. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.04; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-5 Persons entitled to fill prescriptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 5. Persons entitled to fill prescriptions. A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or by a registered institutional practitioner. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.05; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-6 Dispensing of narcotics for maintenance purposes
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 6. Dispensing of narcotic drugs for maintenance purposes. The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of treatment of his dependence upon such drugs in the course of conducting a clinical investigation authorized by State or Federal law in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research" in IC 1971, 35-24.1-1-1(u) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.06; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-7 Schedule II controlled substances; prescription required; exceptions
Authority: IC 35-48-3-1
Affected: IC 35-48

Sec. 7. (a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in subsection (d).

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his or her professional practice without a prescription subject to section 6 of this rule.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by subsection (e), a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided the following:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner).

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in section 4 of this rule, except for the signature of the prescribing individual practitioner.

(3) If the prescribing individual practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his or her phone number as listed in the telephone directory and/or other good faith efforts to assure his or her identity.

(4) Within seven (7) days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of section 4 of this rule, the prescription shall have written on its face “Authorization for Emergency Dispensing”, and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Indiana board of pharmacy if the prescribing individual fails to deliver a written prescription to him or her, failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing individual practitioner.

(e) For the purpose of authorizing an oral prescription of a controlled substance listed in Schedule II of IC 35-48 as amended, “emergency situation” means those situations in which the prescribing practitioner determines the following:

(1) That immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

(2) That no appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under Schedule II of IC 35-48 as amended.

(3) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

(Indiana Board of Pharmacy; Reg 28, Ch VI,Sec 6.11; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2505; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-8 Schedule II controlled substances; refilling prescriptions

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 8. Refilling prescriptions Schedule II [856 IAC 2-2-3]. The refilling of a prescription for a controlled substance listed in Schedule II [856 IAC 2-2-3] is prohibited. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.12; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-9 Schedule II controlled substances; partial filling of prescriptions

Authority: IC 35-48-3-1
Affected: IC 35-48-2-6; IC 35-48-3-9

Sec. 9. (a) The partial filling of a prescription for a controlled substance listed in Schedule II under IC 35-48-2-6, as amended, is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for patients in long term care facilities may be filled in partial quantities to include individual dosage units. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of a Schedule II controlled substance dispensed in all partial fillings must not exceed the total quantity prescribed. A Schedule II prescription, for a patient in a long term care facility, shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication.

(c) A prescription for a Schedule II controlled substance written for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist has a responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription the patient is “terminally ill”. A prescription that is partially filled and does not contain the notation “terminally ill” shall be deemed to have been filled in violation of this section. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of a Schedule II controlled substance dispensed in all partial fillings must not exceed the total quantity prescribed. A Schedule II prescription for a patient with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication. (Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.13; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 8, 1986, 9:55 a.m.: 9 IR 2205; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-10 Schedule II controlled substances; label information; exceptions

Authority: IC 35-48-3-1

Affected: IC 35-48-3-9

Sec. 10. Labeling of substances. (a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II [856 IAC 2-2-3] shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and the cautionary statement, "Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed", any others if any, contained in such prescription or required by law.

(b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II [856 IAC 2-2-3] is prescribed for administration to an ultimate user who is institutionalized; Provided, That:

(1) Not more than 7-day supply of the controlled substance listed in Schedule II [856 IAC 2-2-3] is dispensed at one time;

(2) The controlled substance listed in schedule II [856 IAC 2-2-3] is not in the possession of the ultimate user prior to the administration; and

(3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in schedule II [856 IAC 2-2-3]; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.14; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-11 Schedule II controlled substances; retention of prescriptions (Repealed)

Sec. 11. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-6-12 Schedules III and IV controlled substances

Authority: IC 35-48-3-1

Affected: IC 35-48-3-9

Sec. 12. (a) A pharmacist may dispense a controlled substance listed in Schedule III or IV under 856 IAC 2-2-4 or 856 IAC 2-2-5, which is a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner or a practitioner's authorized agent and promptly reduced to writing by the pharmacist containing all information required in 856 IAC 2-6-4 [section 4 of this rule], except for the signature of the prescribing individual practitioner.

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule III or IV under 856 IAC 2-2-4 or 856 IAC 2-2-5 in the course of his or her professional practice without a prescription, subject to 856 IAC 2-6-6 [section 6 of this rule].

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV under 856 IAC 2-2-4 or 856 IAC 2-2-5 pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in 856 IAC 2-6-4 [section 4 of this rule], except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user, subject to 856 IAC 2-6-6 [section 6 of this rule]. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.21; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)

856 IAC 2-6-13 Schedules III, IV, and V controlled substances; refilling prescriptions; retrievable information

Authority: IC 35-48-3-1

Affected: IC 35-48-2; IC 35-48-3-9

Sec. 13. (a) No prescription for a controlled substance listed in Schedule III (IC 35-48-2-8), Schedule IV (IC 35-48-2-10), or Schedule V (IC 35-48-2-12) shall be filled or refilled more than six (6) months after the date on which such prescription was issued, and no such prescription shall be authorized to be refilled more than five (5) times.

(b) Each refill of a prescription shall be recorded by one (1) of the following methods:

(1) On the back of the original prescription and, if used, a uniformly maintained, readily retrievable record such as a medication record or patient profile.

(2) In the storage memory of an electronic data processing system if such board approved system is used in the pharmacy.

(c) The following prescription information shall be retrievable by using or entering the serial number of the prescription:

(1) The name (and strength if applicable) and dosage form of the controlled substance.

(2) The date on which the prescription was written or phoned and reduced to writing by the pharmacist.

(3) The date of original filling and the date or dates of all refills.

(4) A notation or notations for the original filling and each and every subsequent refilling sufficient to identify the dispensing pharmacist.

(5) The total number of refills originally authorized and remaining for each individual prescription.

If the pharmacist does nothing more than date and initial the prescription to indicate a refill has been dispensed, the pharmacist shall be deemed to have dispensed a refill for the full face amount (that is the originally prescribed amount) of the prescription.

(d) Additional refills for prescriptions for controlled substances listed in Schedule III (IC 35-48-2-8), Schedule IV (IC 35-48-2-10), or Schedule V (IC 35-48-2-12) may be added to the original prescription on an oral authorization transmitted to the pharmacist by the original prescribing practitioner providing the following conditions are met:

(1) The total quantity authorized does not exceed the original face amount of the prescription and five (5) total refills, and none of the refills is for more dose units or a larger quantity than the original face amount of the prescription.

(2) No dispensing takes place pursuant to the original prescription more than six (6) months after the date of the original issue of the prescription.

(3) The pharmacist receiving the oral authorization records that authorization on the reverse of the original prescription, or in a readily retrievable record, and the following information:

(A) The date of the authorization.

(B) The number of the dose units or quantity authorized.

(C) The number of additional refills authorized.

(D) The initials of the pharmacist receiving the oral authorization.

(e) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five (5) refill, six (6) month limitation. (Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.22; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 20, 1988, 9:30 a.m.: 11 IR 3564; filed Jul 5, 1995, 10:00 a.m.: 18 IR 2783; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-14 Schedules III, IV and V controlled substances; partial filling of prescriptions

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 14. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V in the Controlled Substance Act, IC 35-48 as amended is permissible, provided that:

(a) each partial filling is recorded in the same manner as a refilling,

(b) the total quantity dispensed pursuant to an individual prescription including the original and all subsequent partial refills does not exceed the total quantity prescribed, and

(c) no dispensing occurs more than six (6) months after the date on which the prescription was issued.

(Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.23; filed Jul 9, 1974, 9:29 am: Unpublished; filed May 20, 1988, 9:30 am: 11 IR 3565; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-15 Schedules III and IV controlled substances; label information; exceptions

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 15. Labeling of substances. (a) The pharmacist filling a prescription for a controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statement, "Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed", and other if any, contained in such prescription as required by law.

(b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] is dispensed at one time;

(2) The controlled substance listed in schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] is not in the possession of the ultimate user prior to administration;

(3) The institution maintains appropriate safeguards and records, the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5]; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.24; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-16 Schedules III and IV controlled substances; retention of prescriptions

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 16. Filing prescriptions. All prescriptions for controlled substances listed in Schedules III and IV [856 IAC 2-2-4 or 856 IAC 2-2-5] shall be kept in accordance with section 4.01 [856 IAC 2-4-1] of these regulations. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.25; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-17 Schedule V controlled substances; prescription requirements; refilling; exceptions

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 17. Requirement of prescription. (a) A pharmacist may dispense a controlled substance listed in Schedule V [856 IAC 2-2-6] pursuant to a prescription as required for controlled substances listed in Schedules III and IV [856 IAC 2-2-4 and 856 IAC 2-2-5] in section 6.21 [856 IAC 2-6-12]. A prescription for a controlled substance listed in Schedule V [856 IAC 2-2-6] may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with section 6.24 [856 IAC 2-6-15] and file the prescription in accordance with section 6.25 [856 IAC 2-6-16].

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule V [856 IAC 2-2-6] in the course of his professional practice without a prescription, subject to section 6.24 [856 IAC 2-6-15].

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V [856 IAC 2-2-6] only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in section 6.04 [856 IAC 2-6-4] except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to section 6.24 [856 IAC 2-6-15]. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.31; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-18 Dispensing without prescription; delivery of devices

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 18. (a) A controlled substance listed in Schedule V in the Controlled Substance Act, IC 35-48 which does not require a prescription under federal, state or local law or a device known as a hypodermic syringe and/or needle for human use may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(1) such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in his [sic.] section, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist);

(2) no more than:

(i) 240 cc. (8 ounces) or 48 dosage units of any substance containing opium;

(ii) 120 cc. (4 ounces) or 24 dosage units of any other substance nor more than 48 dosage units may be dispensed at retail to the same purchaser in any given 48-hour period;

(3) the purchaser is at least eighteen (18) years of age. However, if the item being purchased is a device known as a hypodermic syringe and/or needle for human use, the age restriction shall not apply;

(4) the pharmacist requires every purchaser of a controlled substance or device as described in 856 IAC 2-6-18(a) not known to the pharmacist to furnish suitable identification (including proof of age where appropriate); and

(5) separate bound record books for dispensing of:

(i) controlled substances; and

(ii) devices under this section;

are maintained by the pharmacist. These books shall contain the name and address of the purchaser, the name and quantity of controlled substance or devices purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance or devices to the purchaser these books shall be maintained in accordance with the recordkeeping requirements of 856 IAC 2-4-1.

(b) Delivery of devices, as described above, to inpatients of institutions is exempt from this section.

(c) The delivery of a device known as a hypodermic syringe-needle other than by a pharmacist in a licensed pharmacy or a licensed practitioner in his lawful place of practice is prohibited. (Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.32; filed Jul 9, 1974, 9:29 am: Unpublished; filed May 20, 1988, 9:30 am: 11 IR 3565; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

End of section

IC 25-1-9

Chapter 9. Health Professions Standards of Practice

IC 25-1-9-1

Sec. 1. As used in this chapter, "board" means any of the following:

(1) Board of chiropractic examiners (IC 25-10-1).

(2) State board of dentistry (IC 25-14-1).

(3) Indiana state board of health facility administrators (IC 25-19-1).

(4) Medical licensing board of Indiana (IC 25-22.5-2).

(5) Indiana state board of nursing (IC 25-23-1).

(6) Indiana optometry board (IC 25-24).

(7) Indiana board of pharmacy (IC 25-26).

(8) Board of podiatric medicine (IC 25-29-2-1).

(9) Board of environmental health specialists (IC 25-32).

(10) Speech-language pathology and audiology board (IC 25-35.6-2).

(11) State psychology board (IC 25-33).

(12) Indiana board of veterinary medical examiners (IC 15-5-1.1).

(13) Indiana physical therapy committee (IC 25-27-1).

(14) Respiratory care committee (IC 25-34.5).

(15) Occupational therapy committee (IC 25-23.5).

(16) Social worker, marriage and family therapist, and mental health counselor board (IC 25-23.6).

(17) Physician assistant committee (IC 25-27.5).

(18) Indiana athletic trainers board (IC 25-5.1-2-1).

(19) Indiana dietitians certification board (IC 25-14.5-2-1).

(20) Indiana hypnotist committee (IC 25-20.5-1-7).

As added by P.L.152-1988, SEC.1. Amended by P.L.242-1989, SEC.7; P.L.238-1989, SEC.7; P.L.186-1990, SEC.7; P.L.48-1991, SEC.20; P.L.227-1993, SEC.7; P.L.33-1993, SEC.14; P.L.213-1993, SEC.4; P.L.1-1994, SEC.122; P.L.124-1994, SEC.6; P.L.175-1997, SEC.6; P.L.147-1997, SEC.10; P.L.84-1998, SEC.5; P.L.24-1999, SEC.6.

IC 25-1-9-2

Sec. 2. As used in this chapter, "practitioner" means an individual who holds:

(1) an unlimited license, certificate, or registration;

(2) a limited or probationary license, certificate, or registration;

(3) a temporary license, certificate, registration, or permit;

(4) an intern permit; or

(5) a provisional license;

issued by the board regulating the profession in question, including a certificate of registration issued under IC 25-20.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-3

Sec. 3. As used in this chapter, "license" includes a license, certificate, registration, or permit.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-3.5

Sec. 3.5. As used in this chapter, "sexual contact" means:

(1) sexual intercourse (as defined in IC 35-41-1-26);

(2) deviate sexual conduct (as defined in IC 35-41-1-9); or

(3) any fondling or touching intended to arouse or satisfy the sexual desires of either the individual performing the fondling or touching or the individual being fondled or touched.

As added by P.L.200-2001, SEC.1.

IC 25-1-9-4a

Note: This version of section amended by P.L.200-2001, SEC.2. See also following version of this section amended by P.L.203-2001, SEC.3.

Sec. 4. (a) A practitioner shall conduct the practitioner's practice in accordance with the standards established by the board regulating the profession in question and is subject to the exercise of the disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds:

(1) a practitioner has:

(A) engaged in or knowingly cooperated in fraud or material deception in order to obtain a license to practice;

(B) engaged in fraud or material deception in the course of professional services or activities; or

(C) advertised services in a false or misleading manner;

(2) a practitioner has been convicted of a crime that has a direct bearing on the practitioner's ability to continue to practice competently;

(3) a practitioner has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question;

(4) a practitioner has continued to practice although the practitioner has become unfit to practice due to:

(A) professional incompetence that:

(i) may include the undertaking of professional activities that the practitioner is not qualified by training or experience to undertake; and

(ii) does not include activities performed under IC 16-21-2-9;

(B) failure to keep abreast of current professional theory or practice;

(C) physical or mental disability; or

(D) addiction to, abuse of, or severe dependency upon alcohol or other drugs that endanger the public by impairing a practitioner's ability to practice safely;

(5) a practitioner has engaged in a course of lewd or immoral conduct in connection with the delivery of services to the public;

(6) a practitioner has allowed the practitioner's name or a license issued under this chapter to be used in connection with an individual who renders services beyond the scope of that individual's training, experience, or competence;

(7) a practitioner has had disciplinary action taken against the practitioner or the practitioner's license to practice in any other state or jurisdiction on grounds similar to those under this chapter;

(8) a practitioner has diverted:

(A) a legend drug (as defined in IC 16-18-2-199); or

(B) any other drug or device issued under a drug order (as defined in IC 16-42-19-3) for another person;

(9) a practitioner, except as otherwise provided by law, has knowingly prescribed, sold, or administered any drug classified as a narcotic, addicting, or dangerous drug to a habitue or addict;

(10) a practitioner has failed to comply with an order imposing a sanction under section 9 of this chapter; or

(11) a practitioner has engaged in sexual contact with a patient under the practitioner's care or has used the practitioner-patient relationship to solicit sexual contact with a patient under the practitioner's care.

(b) A practitioner who provides health care services to the practitioner's spouse is not subject to disciplinary action under subsection (a)(11).

(c) A certified copy of the record of disciplinary action is conclusive evidence of the other jurisdiction's disciplinary action under subsection (a)(7).

As added by P.L.152-1988, SEC.1. Amended by P.L.2-1993, SEC.136; P.L.149-1997, SEC.7; P.L.22-1999, SEC.4; P.L.200-2001, SEC.2.

Note: See also following version of this section amended by P.L.203-2001, SEC.3.

IC 25-1-9-4b

Note: This version of section amended by P.L.203-2001, SEC.3. See also preceding version of this section amended by P.L.200-2001, SEC.2.

Sec. 4. (a) A practitioner shall conduct the practitioner's practice in accordance with the standards established by the board regulating the profession in question and is subject to the exercise of the disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds:

(1) a practitioner has:

(A) engaged in or knowingly cooperated in fraud or material deception in order to obtain a license to practice;

(B) engaged in fraud or material deception in the course of professional services or activities; or

(C) advertised services in a false or misleading manner;

(2) a practitioner has been convicted of a crime that has a direct bearing on the practitioner's ability to continue to practice competently;

(3) a practitioner has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question;

(4) a practitioner has continued to practice although the practitioner has become unfit to practice due to:

(A) professional incompetence that:

(i) may include the undertaking of professional activities that the practitioner is not qualified by training or experience to undertake; and

(ii) does not include activities performed under IC 16-21-2-9;

(B) failure to keep abreast of current professional theory or practice;

(C) physical or mental disability; or

(D) addiction to, abuse of, or severe dependency upon alcohol or other drugs that endanger the public by impairing a practitioner's ability to practice safely;

(5) a practitioner has engaged in a course of lewd or immoral conduct in connection with the delivery of services to the public;

(6) a practitioner has allowed the practitioner's name or a license issued under this chapter to be used in connection with an individual who renders services beyond the scope of that individual's training, experience, or competence;

(7) a practitioner has had disciplinary action taken against the practitioner or the practitioner's license to practice in any other state or jurisdiction on grounds similar to those under this chapter;

(8) a practitioner has diverted:

(A) a legend drug (as defined in IC 16-18-2-199); or

(B) any other drug or device issued under a drug order (as defined in IC 16-42-19-3) for another person;

(9) a practitioner, except as otherwise provided by law, has knowingly prescribed, sold, or administered any drug classified as a narcotic, addicting, or dangerous drug to a habitue or addict;

(10) a practitioner has failed to comply with an order imposing a sanction under section 9 of this chapter; or

(11) a practitioner who is a participating provider of a health maintenance organization has knowingly collected or attempted to collect from a subscriber or enrollee of the health maintenance organization any sums that are owed by the health maintenance organization.

(b) A certified copy of the record of disciplinary action is conclusive evidence of the other jurisdiction's disciplinary action under subsection (a)(7).

As added by P.L.152-1988, SEC.1. Amended by P.L.2-1993, SEC.136; P.L.149-1997, SEC.7; P.L.22-1999, SEC.4; P.L.203-2001, SEC.3.

Note: See also preceding version of this section amended by P.L.200-2001, SEC.2.

IC 25-1-9-5

Sec. 5. In addition to section 4 of this chapter, a practitioner licensed to practice optometry is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds a practitioner has accepted employment to practice optometry from a person other than:

(1) a corporation formed by an optometrist under IC 23-1.5; or

(2) an individual who is licensed as an optometrist under this article and whose legal residence is in Indiana.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-6

Sec. 6. In addition to section 4 of this chapter, a practitioner licensed to practice veterinary medicine or registered as a veterinary technician is subject to the exercise of the disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds a practitioner has engaged in cruelty to animals.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-6.5

Sec. 6.5. (a) In addition to section 4 of this chapter, a practitioner licensed to practice chiropractic is subject to the exercise of the disciplinary sanctions under section 9 of this chapter if, after a hearing, the board regulating the profession finds a practitioner has:

(1) waived a payment of a deductible or a copayment required to be made to the practitioner by a patient under the patient's insurance or health care plan; and

(2) advertised the waiver of a payment described in subdivision (1).

(b) This section does not apply to the waiver of a deductible or a copayment by a practitioner if:

(1) the practitioner determines chiropractic service is necessary for the immediate health and welfare of a patient;

(2) the practitioner determines the payment of a deductible or a copayment would create a substantial financial hardship for the patient; and

(3) the waiver is based on the evaluation of the individual patient and is not a regular business practice of the practitioner.

As added by P.L.151-1989, SEC.9.

IC 25-1-9-6.7

Sec. 6.7. In addition to the actions listed under section 4 of this chapter that subject a practitioner to the exercise of disciplinary sanctions, a practitioner who is licensed under IC 25-23.6 is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board regulating the profession finds that the practitioner has:

(1) performed any therapy that, by the prevailing standards of the mental health professions in the community where the services were provided, would constitute experimentation on human subjects, without first obtaining full, informed, and written consent;

(2) failed to meet the minimum standards of performance in professional activities when measured against generally prevailing peer performance in professional activities, including the undertaking of activities that the practitioner is not qualified by training or experience to undertake;

(3) performed services, including any duties required of the individual under IC 31, in reckless disregard of the best interests of a patient, a client, or the public;

(4) without the consent of the child's parent, guardian, or custodian, knowingly participated in the child's removal or precipitated others to remove a child from the child's home unless:

(A) the child's physical health was endangered due to injury as a result of the act or omission of the child's parent, guardian, or custodian;

(B) the child had been or was in danger of being a victim of an offense under IC 35-42-4, IC 35-45-4-1, IC 35-45-4-2, IC 35-46-1-3, IC 35-49-2-2, or IC 35-49-3-2; or

(C) the child was in danger of serious bodily harm as a result of the inability, refusal, or neglect of the child's parent, guardian, or custodian to supply the child with necessary food, shelter, or medical care, and a court order was first obtained;

(5) willfully made or filed a false report or record, failed to file a report or record required by law, willfully impeded or obstructed the filing of a report or record, or induced another individual to:

(A) make or file a false report or record; or

(B) impede or obstruct the filing of a report or record; or

(6) performed a diagnosis (as defined in IC 25-22.5-1-1.1(c));

(7) provided evidence in an administrative or judicial proceeding that had insufficient factual basis for the conclusions rendered by the practitioner;

(8) willfully planted in the mind of the patient suggestions that are not based in facts known to the practitioner; or

(9) performed services outside of the scope of practice of the license issued under IC 25-23.6.

As added by P.L.147-1997, SEC.11. Amended by P.L.2-1998, SEC.65.

IC 25-1-9-6.9

Sec. 6.9. In addition to the actions listed under section 4 of this chapter that subject a practitioner to disciplinary sanctions, a practitioner is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds that the practitioner has:

(1) failed to provide information requested by the bureau; or

(2) knowingly provided false information to the bureau;

for a provider profile required under IC 25-1-5-10.

As added by P.L.211-2001, SEC.2.

IC 25-1-9-7

Sec. 7. The board may order a practitioner to submit to a reasonable physical or mental examination if the practitioner's physical or mental capacity to practice safely is at issue in a disciplinary proceeding.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-8

Sec. 8. Failure to comply with a board order to submit to a physical or mental examination makes a practitioner liable to summary suspension under section 10 of this chapter.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-9

Sec. 9. (a) The board may impose any of the following sanctions, singly or in combination, if it finds that a practitioner is subject to disciplinary sanctions under section 4, 5, 6, 6.7, or 6.9 of this chapter or IC 25-1-5-4:

(1) Permanently revoke a practitioner's license.

(2) Suspend a practitioner's license.

(3) Censure a practitioner.

(4) Issue a letter of reprimand.

(5) Place a practitioner on probation status and require the practitioner to:

(A) report regularly to the board upon the matters that are the basis of probation;

(B) limit practice to those areas prescribed by the board;

(C) continue or renew professional education under a preceptor, or as otherwise directed or approved by the board, until a satisfactory degree of skill has been attained in those areas that are the basis of the probation; or

(D) perform or refrain from performing any acts, including community restitution or service without compensation, that the board considers appropriate to the public interest or to the rehabilitation or treatment of the practitioner.

(6) Assess a fine against the practitioner in an amount not to exceed one thousand dollars ($1,000) for each violation listed in section 4 of this chapter, except for a finding of incompetency due to a physical or mental disability. When imposing a fine, the board shall consider a practitioner's ability to pay the amount assessed. If the practitioner fails to pay the fine within the time specified by the board, the board may suspend the practitioner's license without additional proceedings. However, a suspension may not be imposed if the sole basis for the suspension is the practitioner's inability to pay a fine.

(b) The board may withdraw or modify the probation under subsection (a)(5) if it finds, after a hearing, that the deficiency that required disciplinary action has been remedied, or that changed circumstances warrant a modification of the order.

As added by P.L.152-1988, SEC.1. Amended by P.L.48-1991, SEC.21; P.L.22-1999, SEC.5; P.L.32-2000, SEC.10; P.L.211-2001, SEC.3.

IC 25-1-9-10

Sec. 10. (a) The board may summarily suspend a practitioner's license for ninety (90) days before a final adjudication or during the appeals process if the board finds that a practitioner represents a clear and immediate danger to the public health and safety if the practitioner is allowed to continue to practice. The summary suspension may be renewed upon a hearing before the board, and each renewal may be for ninety (90) days or less.

(b) Before the board may summarily suspend a license that has been issued under IC 15-5-1.1, IC 25-22.5 or IC 25-14, the consumer protection division of the attorney general's office shall make a reasonable attempt to notify a practitioner of a hearing by the board to suspend a practitioner's license and of information regarding the allegation against the practitioner. The consumer protection division of the attorney general's office shall also notify the practitioner that the practitioner may provide a written or an oral statement to the board on the practitioner's behalf before the board issues an order for summary suspension. A reasonable attempt to reach the practitioner is made if the consumer protection division of the attorney general's office attempts to reach the practitioner by telephone or facsimile at the last telephone number of the practitioner on file with the board.

(c) After a reasonable attempt is made to notify a practitioner under subsection (b):

(1) a court may not stay or vacate a summary suspension of a practitioner's license for the sole reason that the practitioner was not notified; and

(2) the practitioner may not petition the board for a delay of the summary suspension proceedings.

As added by P.L.152-1988, SEC.1. Amended by P.L.43-1995, SEC.2; P.L.71-2000, SEC.18.

IC 25-1-9-10.1

Sec. 10.1. The attorney general may retain the services of a clinical consultant or an expert to provide the attorney general with advice concerning the acts that are the subject of a suspension under this chapter.

As added by P.L.43-1995, SEC.3.

IC 25-1-9-11

Sec. 11. The board may reinstate a license which has been suspended under this chapter if, after a hearing, the board is satisfied that the applicant is able to practice with reasonable skill and safety to the public. As a condition of reinstatement, the board may impose disciplinary or corrective measures authorized under this chapter.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-12

Sec. 12. The board may not reinstate a license that has been revoked under this chapter. An individual whose license has been revoked under this chapter may not apply for a new license until seven (7) years after the date of revocation.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-13

Sec. 13. The board shall seek to achieve consistency in the application of the sanctions authorized in this section. Significant departures from prior decisions involving similar conduct must be explained in the board's findings or orders.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-14

Sec. 14. A practitioner may petition the board to accept the surrender of the practitioner's license instead of a hearing before the board. The practitioner may not surrender the practitioner's license without the written approval of the board, and the board may impose any conditions appropriate to the surrender or reinstatement of a surrendered license.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-15

Sec. 15. Practitioners who have been subjected to disciplinary sanctions may be required by a board to pay for the costs of the proceeding. The practitioner's ability to pay shall be considered when costs are assessed. If the practitioner fails to pay the costs, a suspension may not be imposed solely upon the practitioner's inability to pay the amount assessed. These costs are limited to costs for the following:

(1) Court reporters.
(2) Transcripts.
(3) Certification of documents.
(4) Photoduplication.
(5) Witness attendance and mileage fees.
(6) Postage.
(7) Expert witnesses.
(8) Depositions.
(9) Notarizations.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-16

Sec. 16. (a) The board may refuse to issue a license or may issue a probationary license to an applicant for licensure if:

(1) the applicant has been disciplined by a licensing entity of another state or jurisdiction, or has committed an act that would have subjected the applicant to the disciplinary process had the applicant been licensed in Indiana when the act occurred; and

(2) the violation for which the applicant was, or could have been, disciplined has a direct bearing on the applicant's ability to competently practice in Indiana.

(b) Whenever the board issues a probationary license, the board may impose one (1) or more of the following conditions:

(1) Report regularly to the board upon the matters that are the basis of the discipline of the other state or jurisdiction.
(2) Limit practice to those areas prescribed by the board.
(3) Continue or renew professional education.
(4) Engage in community restitution or service without compensation for a number of hours specified by the board.
(5) Perform or refrain from performing an act that the board considers appropriate to the public interest or to the rehabilitation or treatment of the applicant.

(c) The board shall remove any limitations placed on a probationary license under this section if the board finds after a hearing that the deficiency that required disciplinary action has been remedied.

As added by P.L.33-1993, SEC.15. Amended by P.L.32-2000, SEC.11.

IC 25-1-9-17

Sec. 17. The board and the controlled substances advisory committee (IC 35-48-2-1) may require an applicant for licensure to appear before the board or committee before issuing a license.

As added by P.L.33-1993, SEC.16.

IC 25-1-9-18

Sec. 18. (a) If the insurance commissioner forwards to the board the name of a practitioner under IC 34-18-9-4(a) (or IC 27-12-9-4(a) before its repeal), the board shall consider whether:

(1) the practitioner has become unfit to practice under section 4 of this chapter; and
(2) a complaint should be filed under IC 25-1-7-4.

(b) If the board determines that a complaint should be filed under subsection (a), the board must report to the consumer protection division whether the board will schedule the matter:

(1) for informal negotiation under IC 25-1-7-6;
(2) on the board's agenda for a vote requesting that the attorney general prosecute the matter before the board under IC 25-1-7-7; or
(3) on the board's agenda for a vote on summary suspension of the practitioner's license pending prosecution of the matter before the board under IC 25-1-7-7.

(c) A board may designate a board member or staff member to act on behalf of the board under this section.

As added by P.L.43-1995, SEC.4. Amended by P.L.1-1998, SEC.131.

End of section

IC 12-15-35

Chapter 35. Drug Utilization Review

IC 12-15-35-1

Sec. 1. As used in this chapter, "appropriate and medically necessary" means drug prescribing, drug dispensing, and patient medication usage in conformity with the criteria and standards developed under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-2

Sec. 2. As used in this chapter, "board" refers to the drug utilization review board created under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-3

Sec. 3. As used in this chapter, "compendia" means those resources widely accepted by the medical profession in the efficacious use of drugs, including the following sources:

(1) The American Hospital Formulary Services Drug Information.

(2) The U.S. Pharmacopeia-Drug Information.

(3) The American Medical Association Drug Evaluations.

(4) The peer-reviewed medical literature.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-4

Sec. 4. As used in this chapter, "counseling" means the activities conducted by a pharmacist to inform Medicaid recipients about the proper use of drugs as required by the board under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-5

Sec. 5. As used in this chapter, "criteria" means the predetermined and explicitly accepted elements that are used to measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-6

Sec. 6. As used in this chapter, "drug-disease contraindication" means an occurrence in which the therapeutic effect of a drug is adversely altered by the presence of another disease condition.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-7

Sec. 7. As used in this chapter, "drug-drug interaction" means an occurrence in which at least two (2) drugs taken by a recipient leads to clinically significant toxicity that:

(1) is characteristic of one (1) or any of the drugs present; or

(2) leads to the interference with the effectiveness of one (1) or any of the drugs.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-8

Sec. 8. As used in this chapter, "drug utilization review" or "DUR" means the program designed to measure and assess on a retrospective and a prospective basis the proper use of outpatient drugs in the Medicaid program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-9

Sec. 9. As used in this chapter, "intervention" means an action taken by the board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices or utilization of drugs.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-10

Sec. 10. As used in this chapter, "overutilization or underutilization" means the use of a drug in such quantities where the desired therapeutic goal is not achieved.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-11

Sec. 11. As used in this chapter, "pharmacist" means an individual who is licensed as a pharmacist in Indiana under IC 25-26.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-12

Sec. 12. As used in this chapter, "physician" means an individual who is licensed to practice medicine in Indiana under IC 25-22.5.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-13

YAMD.1992

Sec. 13. As used in this chapter, "prospective DUR" means the part of the drug utilization review program that:

(1) is to occur before the drug is dispensed;

(2) is designed to screen for potential drug therapy problems based on explicit and predetermined criteria and standards that are developed on an ongoing basis with professional input; and

(3) is to provide for the counseling of recipients about the proper use of drugs.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-14

IC 12-15-35-14 Sec. 14. As used in this chapter, "retrospective DUR" means the part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against predetermined and explicit criteria and standards that are developed on an ongoing basis with professional input.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-15

Sec. 15. As used in this chapter, "standards" means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on the Medicaid recipient database.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-16

Sec. 16. As used in this chapter, "SURS" refers to the surveillance utilization review system of the Medicaid program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-17

Sec. 17. As used in this chapter, "therapeutic appropriateness" means drug prescribing based on rational drug therapy that is consistent with the criteria and standards developed under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-18

Sec. 18. As used in this chapter, "therapeutic duplication" means the prescribing and dispensing of:

(1) the same drug; or

(2) at least two (2) drugs from the same therapeutic class;

where overlapping periods of drug administration are involved and where such prescribing or dispensing is not medically indicated.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-18.5

Sec. 18.5. This chapter applies to any contractor or vendor of the state responsible for providing or managing any part of the Medicaid outpatient drug program.

As added by P.L.76-1994, SEC.2.

IC 12-15-35-18.7

Sec. 18.7. A formulary established by a Medicaid managed care organization is subject to sections 46 and 47 of this chapter.

As added by P.L.231-1999, SEC.2.

IC 12-15-35-19

Sec. 19. The drug utilization review board is established.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-20

Sec. 20. The board is composed of the following:

(1) Four (4) individuals licensed and actively engaged in the practice of medicine or osteopathic medicine in Indiana under IC 25-22.5.

(2) Four (4) individuals licensed under IC 25-26 and actively engaged in the practice of pharmacy in Indiana.

(3) One (1) individual with expertise in therapeutic pharmacology who is neither a physician or a pharmacist.

(4) A representative of the office who shall serve as an ex-officio nonvoting member of the board.

(5) One (1) individual who:

(A) is employed by a health maintenance organization that has a pharmacy benefit; and

(B) has expertise in formulary development and pharmacy benefit administration.

The individual appointed under this subdivision may not be employed by a health maintenance organization that is under contract or subcontract with the state to provide services to Medicaid recipients under this article.

(6) One (1) individual who is a health economist.

As added by P.L.75-1992, SEC.19. Amended by P.L.231-1999, SEC.3.

IC 12-15-35-20.1

Sec. 20.1. (a) Each board member shall fully disclose any potential conflicts of interest, financial or otherwise, relating to an issue that comes before the board for recommendation or other action.

(b) A board member may not vote on a recommendation or other action if the member or the member's employer has a conflict of interest, financial or otherwise, in the outcome of the vote.

(c) A board member who may not vote on a recommendation or other action under subsection (b) may still participate in any discussions regarding the recommendation or other action.

As added by P.L.231-1999, SEC.4.

IC 12-15-35-21

Sec. 21. (a) The members of the board shall be appointed by the governor and serve a term of three (3) years.

(b) The governor shall fill a vacancy on the board by appointing a new member to serve the remainder of the unexpired term.

(c) The governor may remove a member for cause.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-22

Sec. 22. Board members must have expertise in one (1) or more of the following:

(1) Clinically appropriate prescribing of outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of outpatient drugs.

(3) Drug utilization review, evaluation, and intervention.

(4) Medical quality assurance.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-23

Sec. 23. In making the physician appointments, the governor shall provide for geographic balance.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-24

Sec. 24. An individual appointed to the board may be reappointed upon the completion of the individual's term.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-25

Sec. 25. (a) The board shall annually elect a chairman from the members of the board.

(b) The chairman may be re-elected to serve consecutive terms as chairman.

(c) A member of the board who is not a state employee is entitled to the minimum salary per diem as provided by IC 4-10-11-2.1(b). Each member of the board is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties as provided in the state travel policies and procedures established by the Indiana department of administration and the budget agency.

(d) Each member of the board who is a state employee is entitled to reimbursement for traveling expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the Indiana department of administration and approved by the budget agency.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-26

Sec. 26. The secretary shall provide additional staff to the board.

As added by P.L.75-1992, SEC.19. Amended by P.L.291-2001, SEC.162.

IC 12-15-35-27

Sec. 27. The board is responsible for the oversight of the retrospective and prospective DUR program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-28

Sec. 28. The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for

physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.3.

IC 12-15-35-29

Sec. 29. (a) A quorum consists of six (6) voting members of the board.

(b) DUR criteria and standards for appropriate prescribing may only be implemented with the approval of a majority of the quorum of the board. The majority vote must include at least three (3) of the four (4) physician members of the board and may allow the board to accept deviations from the standards on a case-by-case basis.

As added by P.L.75-1992, SEC.19. Amended by P.L.231-1999, SEC.5.

IC 12-15-35-30

Sec. 30. The criteria and standards developed under section 28(3) of this chapter for appropriate prescribing that are implemented must reflect the local practices of physicians to monitor the following:

(1) Therapeutic appropriateness.

(2) Overutilization or underutilization.

(3) Therapeutic duplication.

(4) Drug-disease contraindications.

(5) Drug-drug interactions.

(6) Incorrect drug dosage or duration of drug treatment.

(7) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-31

Sec. 31. (a) An intervention developed under section 28(4) of this chapter that involves a physician must be approved by at least three (3) of the four (4) physician members of the board before implementation.

(b) An intervention that involves a pharmacist must be approved by at least three (3) of the four (4) pharmacist members of the board before implementation.

(c) Interventions include the following:

(1) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the board's duties and powers.

(2) Written, oral, or electronic reminders of recipient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care.

(3) Use of face-to-face discussions between experts in drug therapy and the prescriber or pharmacist who has been targeted for educational intervention.

(4) Intensified reviews or monitoring of selected prescribers or pharmacists.

(5) The creation of an educational program using data provided through DUR to provide for active and ongoing educational outreach programs to improve prescribing and dispensing practices.

(6) The timely evaluation of interventions to determine if the interventions have improved the quality of care.

(7) The review of case profiles before the conducting of an intervention.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-32

(*Repealed by P.L.76-1994, SEC.7.)*

IC 12-15-35-32.1

YAMD.1994

Sec. 32.1. The annual report under section 28 of this chapter shall include information on the following:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use and any changes in criteria.

(4) A description of the nature and scope of the retrospective DUR program.

(5) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(6) An estimate of the cost savings generated as a result of the DUR program including savings to the Medicaid drug program attributable to the prospective and retrospective DUR.

(7) An overview of the fiscal impact of the DUR program on other areas of the Medicaid program.

(8) A quantifiable assessment of how DUR has improved quality of care.

(9) A summary of the total number of prescriptions reviewed by drug therapeutic class.

As added by P.L.76-1994, SEC.4.

IC 12-15-35-33

(*Repealed by P.L.1-1993, SEC.132.)*

IC 12-15-35-34

Sec. 34. (a) Information that identifies an individual collected under this chapter is confidential and may not be disclosed by the board.

(b) The board may have access to identifying information for purposes of carrying out intervention activities. The identifying information may not be released to anyone other than a member of the board.

(c) The board may release cumulative non-identifying information for purposes of legitimate research.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-35

Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(b) Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug

monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least thirty (30) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least thirty (30) days but not more than sixty (60) days after the notification.

(3). Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(c) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(d) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.5; P.L.231-1999, SEC.6.

IC 12-15-35-36

Sec. 36. The board may establish advisory committees to assist the board in carrying out the board's duties under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-37

Sec. 37. The board shall, in cooperation with the secretary, include in the Medicaid state plan the creation and implementation of a retrospective and prospective DUR program for Medicaid outpatient drugs to ensure that the prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-38

Sec. 38. The retrospective and prospective DUR program shall be operated under the guidelines and procedures established by the board under section 29 of this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-39

Sec. 39. Retrospective DUR must:

(1) be based on the guidelines established by the board; and

(2) use the mechanized drug claims processing and information retrieval system to analyze claims data to do the following:

(A) Identify patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care.

(B) Assess data on drug use against explicit predetermined standards that are based on the compendia and other sources to monitor the following:

(i) Therapeutic appropriateness.

(ii) Overutilization or underutilization.

(iii) Therapeutic duplication.

(iv) Drug-disease contraindications.

(v) Drug-drug interactions.

(vi) Incorrect drug dosage or duration of drug treatment.

(vii) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-40

Sec. 40. Prospective DUR must be based on the guidelines established by the board and must provide that prior to the prescription being filled or delivered a review will be conducted by the pharmacist at the point of sale to screen for potential drug therapy problems resulting from the following:

(1) Therapeutic duplication.

(2) Drug-drug interactions.

(3) Incorrect dosage and duration of treatment.

(4) Drug-allergy interactions.

(5) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-41

Sec. 41. The activities of the board in carrying out this chapter are covered under IC 34-30-15.

As added by P.L.75-1992, SEC.19. Amended by P.L.1-1998, SEC.103.

IC 12-15-35-42

Sec. 42. (a) The board may meet in an executive session for purposes of reviewing DUR data or to conduct or to discuss activity as provided for in IC 5-14-1.5-6.1.

(b) The board shall also conduct regular public meetings to gather input from the public on the operation of the DUR program.

(c) The board shall meet monthly to implement its duties under this chapter.

As added by P.L.75-1992, SEC.19. Amended by P.L.291-2001, SEC.163.

IC 12-15-35-43

Sec. 43. Confidential data or information obtained by pharmacists as part of prospective DUR are confidential but may be released to prescribers or others according to procedures established by the board.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-44

Sec. 44. A person who does not comply with the confidentiality provisions under section 34 of this chapter commits a Class A misdemeanor.

As added by P.L.75-1992, SEC.19. Amended by P.L.1-1993, SEC.133.

IC 12-15-35-45

Sec. 45. (a) The chairman of the board, subject to the approval of the board members, may appoint an advisory committee to make

recommendations to the board on the development of a Medicaid outpatient drug formulary.

(b) If the office decides to establish a Medicaid outpatient drug formulary, the formulary shall be developed by the board.

(c) A formulary used by a Medicaid managed care organization is subject to sections 46 and 47 of this chapter.

As added by P.L.76-1994, SEC.6. Amended by P.L.231-1999, SEC.7.

IC 12-15-35-46

Sec. 46. (a) This section applies to a managed care organization that enters into an initial contract with the office to be a Medicaid managed care organization after May 13, 1999.

(b) Before a Medicaid managed care organization described in subsection (a) implements a formulary, the managed care organization shall submit the formulary to the office at least thirty-five (35) days before the date that the managed care organization implements the formulary for Medicaid recipients.

(c) The office shall forward the formulary to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will review a Medicaid managed care organization's proposed formulary at a particular board meeting. The notification shall contain the following information:

(1) A statement of the date, time, and place at which the board meeting will be convened.

(2) A general description of the subject matter of the board meeting.

(3) An explanation of how a copy of the formulary to be discussed may be obtained.

The board shall meet to review the formulary at least thirty (30) days but not more than sixty (60) days after the notification.

(e) In reviewing the formulary, the board shall do the following:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that the use of the formulary will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Make a determination that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary;

(B) a process is in place through which a Medicaid member has access to medically necessary drugs; and

(C) the managed care organization otherwise meets the requirements of IC 27-13-38.

(f) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendation to the office.

(g) Within thirty (30) days after the board meeting, the board shall make a recommendation to the office regarding whether the proposed formulary should be approved, disapproved, or modified.

(h) The office shall rely significantly on the clinical expertise of the board. If the office does not agree with the recommendations of the board, the office shall, at a public meeting, discuss the disagreement with the board and present any additional information to the board for the board's consideration. The board's consideration of additional information must be conducted at a public meeting.

(i) Based on the final recommendations of the board, the office shall approve, disapprove, or require modifications to the Medicaid managed care organization's proposed formulary. The office shall notify the managed care organization of the office's decision within fifteen (15) days of receiving the board's final recommendation.

(j) The managed care organization must comply with the office's decision within sixty (60) days after receiving notice of the office's decision. (k) Notwithstanding the other provisions of this section, the office may temporarily approve a Medicaid managed care organization's proposed formulary pending a final recommendation from the board.

As added by P.L.231-1999, SEC.8.

IC 12-15-35-47

Sec. 47. (a) This section applies to the following changes to a formulary used by a Medicaid managed care organization for Medicaid recipients:

(1) Removing one (1) or more drugs from the formulary.

(2) Placing new restrictions on one (1) or more drugs on the formulary.

(b) Before a Medicaid managed care organization makes a change described in subsection (a), the managed care organization shall submit the proposed change to the office.

(c) The office shall forward the proposed change to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will:

(1) review the proposed change; and

(2) consider evidence and credible information provided to the board;

at the board's regular board meeting before making a recommendation to the office regarding whether the proposed change should be approved or disapproved.

(e) Based on the final recommendation of the board, the office may approve or disapprove the proposed change. If a proposed change is not disapproved within ninety (90) days after the date the managed care organization submits the proposed change to the office, the managed care organization may implement the change to the formulary.

(f) A Medicaid managed care organization:

(1) may add a drug to the managed care organization's formulary without the approval of the office; and

(2) shall notify the office of any addition to the managed care organization's formulary within thirty (30) days after making the addition.

As added by P.L.231-1999, SEC.9.

IC 12-15-35-49

Sec. 49. (a) The office shall provide the board with information necessary for the board to carry out its duties under this chapter.

(b) The office shall provide the information required under subsection (a):

(1) when requested by the board; and

(2) in a timely manner.

As added by P.L.291-2001, SEC.164.

End of section.

IC 16-42-3

Chapter 3. Uniform Food, Drug, and Cosmetic Act: Adulteration and Misbranding of Drugs or Devices

IC 16-42-3-1

Sec. 1. As used in this chapter, "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance that is produced by microorganisms and that has the capacity to inhibit or destroy microorganisms in dilute solution, including the chemically synthesized equivalent of the substance.
As added by P.L.2-1993, SEC.25.

IC 16-42-3-2

Sec. 2. As used in this chapter, "established name", with respect to a drug or ingredient of a drug, means:

(1) the applicable official name designated under Section 508 of the Federal Act;

(2) if there is no official name and the drug or the ingredient is an article recognized in an official compendium, the official title of the drug or ingredient in the compendium; or

(3) if neither subdivision (1) nor (2) applies, the common or usual name, if any, of the drug or the ingredient.

However, when subdivision (2) applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia applies unless the article is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia applies.
As added by P.L.2-1993, SEC.25.

IC 16-42-3-2.5

Sec. 2.5. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.
As added by P.L.137-1996, SEC.70.

IC 16-42-3-3

Sec. 3. A drug or device is considered to be adulterated under the following conditions:

(1) If the drug or device consists in whole or in part of any filthy, putrid, or decomposed substance.

(2) If the drug or device has been produced, prepared, packed, or held under unsanitary conditions under which the drug or device may have been contaminated with filth or made injurious to health.

(3) If the methods used in or the facilities or controls used for a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that:

(A) the drug meets the requirements of this article as to safety; and

(B) the drug:

(i) has the identity and strength; and

(ii) meets the quality and purity characteristics;

that the drug purports or is represented to possess.

(4) If a drug's container is composed in whole or in part of any poisonous or deleterious substance that may make the contents injurious to health.

(5) If:

(A) a drug bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of IC 16-42-2-5; or

(B) a color additive, the intended use of which in or on drugs is for purposes of coloring only, is unsafe under IC 16-42-2-5.

(6) If:

(A) the drug or device purports to be or is represented as a drug, the name of which is recognized in an official compendium; and

(B) the strength of the drug differs from or the drug's quality or purity falls below the standard set forth in that compendium;

the determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium or, in the absence or inadequacy of such tests or methods of assay, those tests or methods prescribed by the federal security administrator in regulations promulgated under the Federal Act. A drug defined in an official compendium is not considered to be adulterated under this subdivision because the drug differs from the standard of strength, quality, or purity set forth in the compendium if the drug's difference in strength, quality, or purity from the standard is plainly stated on the drug's label. If a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia unless the drug is labeled and offered for sale as a homeopathic drug. In the latter case, the drug is subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(7) If:

(A) the drug or device is not subject to the provisions of subdivision (6); and

(B) the drug's or device's strength differs from or the drug's or device's purity or quality falls below that which the drug or device purports or is represented to possess.

(8) If the drug or device is a drug and any substance has been:

(A) mixed or packed with the drug or device so as to reduce the drug's or device's quality or strength; or

(B) substituted wholly or in part for the drug.
As added by P.L.2-1993, SEC.25.

IC 16-42-3-4

Sec. 4. A drug or device is considered to be misbranded under any of the following conditions:

(1) If the labeling of the drug or device is false or misleading in any way.

(2) If the drug or device is in package form unless the drug or device bears a label containing:

(A) the name and place of business of the manufacturer, packer, or distributor; and

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

However, under clause (B) reasonable variations shall be permitted and exemptions as to small packages shall be established by rules adopted by the state department.

(3) If any word, statement, or other information required to appear on the label or labeling, under this chapter or a rule adopted under IC 16-42-1-2 is not prominently placed on the drug or device with conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms that make the label likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) If the drug or device:

(A) is for use by humans; and

(B) contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, methamphetamine, or sulphonmethane, or any chemical derivative of such substance, which derivative after investigation has been found to be and is designated as habit forming, by rules adopted by the state department under IC 16-42-1 through IC 16-42-4 or by regulations issued under 21 U.S.C. 352(d);

unless the label on the drug or device bears the name and quantity or proportion of that substance or derivative and the statement "Warning . May Be Habit Forming".

(5) If a drug, unless the following conditions are met:

(A) The label on the drug bears, to the exclusion of any other nonproprietary name except the applicable systematic chemical name or the chemical formula, the following:

(i) The established name of the drug, if any.

(ii) If the drug is fabricated from at least two (2) ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of those substances contained in the drug. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subdivision, applies only to prescription drugs.

(B) If a prescription drug, the established name of the drug or ingredient on the label (and on any labeling on which a name for the drug or ingredient is used) is printed prominently and in type at least half as large as that used for any proprietary name or designation for the drug or ingredient.

However, to the extent that compliance with the requirements of clause (A)(ii) or clause (B) is impracticable, exemptions shall be allowed under rules adopted by the state department or by regulations promulgated under the Federal Act.

(6) Unless the drug's or device's labeling bears:

(A) adequate directions for use; and

(B) adequate warnings against use in those pathological conditions or by children where the drug's or device's use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in the manner and form that is necessary for the protection of users.

However, if any requirement of clause (A) as applied to any drug or device is not necessary for the protection of the public health, the state department shall adopt rules exempting the drug or device from that requirement.

(7) If a drug purports to be a drug the name of which is recognized in an official compendium, unless the drug is packaged and labeled as prescribed in the compendium. However, the method of packing may be modified with the consent of the state department in accordance with regulations promulgated by the federal security administrator under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless the drug is labeled and offered for sale as a homeopathic drug. In that case the drug is subject to the Homeopathic Pharmacopoeia of the United States and not to the United States Pharmacopoeia.

(8) If a drug or device has been found by the federal security administrator or the state department to be a drug liable to deterioration, unless the drug or device is packaged in a form and manner and the drug's or device's label bears a statement of such precautions as the federal security administrator or the state department requires by rule or regulation as necessary for the protection of the public health. A rule or regulation may not be established for any drug recognized in an official compendium until the federal security administrator or the state department informs the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and that body fails within a reasonable time to prescribe requirements.

(9) If a drug's container is made, formed, or filled as to be misleading.

(10) If a drug is an imitation of another drug.

(11) If a drug is offered for sale under the name of another drug.

(12) If a drug is or purports to be or is represented to be a drug composed wholly or partly of insulin, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 506 of the Federal Act; and

(B) the certificate or release is in effect with respect to the drug.

(13) If a drug is or purports to be or is represented to be a drug composed wholly or partly of any kind of penicillin, streptomycin, chloretetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative of those drugs, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 507 of the Federal Act; and

(B) the certificate or release is in effect with respect to that drug.

However, this subdivision does not apply to any drug or class of drugs exempted by regulations promulgated under Section 507(c) or 507(d) of the Federal Act.

(14) If a drug or device is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug or device.

(15) Under the conditions described in section 6 of this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.17-2001, SEC.3.

IC 16-42-3-5

Sec. 5. A drug or device that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the drug or device was originally processed or packed, is exempt from the labeling and packaging requirements of IC 16-42-1 through IC 16-42-4 while the drug or device is in transit in intrastate commerce from one (1) establishment to the other if the transit is made in good faith for completion purposes only. However, the drug or device is otherwise subject to the applicable provisions of IC 16-42-1 through IC 16-42-4.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-6

Sec. 6. (a) This section applies to a drug intended for use by humans that:

(1) is a habit-forming drug to which section 4(4) of this chapter applies;

(2) because of:

(A) the drug's toxicity or other potential for harmful effect;

(B) the method of the drug's use; or

(C) the collateral measures necessary to the drug's use;

is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or

(3) is limited by an approved application under Section 505 of the Federal Act or section 7 or 8 of this chapter to use under the professional supervision of a practitioner licensed by law to administer the drug.

(b) A drug described in subsection (a) may be dispensed only:

(1) upon a written prescription of a practitioner licensed by law to administer the drug;

(2) upon an oral prescription of the practitioner that is reduced promptly to writing and filed by the pharmacist; or

(3) by refilling a written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order that is reduced promptly to writing and filed by the pharmacist.

(c) If a prescription for a drug described in subsection (a) does not indicate how many times the prescription may be refilled, if any, the prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner.

(d) The act of dispensing a drug contrary to subsection (a), (b), or (c) is considered to be an act that results in a drug being misbranded while held for sale.

(e) A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer the drug is exempt from the requirements of section 4(2), 4(3), 4(4), 4(5), 4(6), 4(7), 4(8), and 4(9) of this chapter if the drug bears a label containing the following:

(1) The name and address of the dispenser.

(2) The serial number and date of the prescription or of the prescription's filling.

(3) The name of the drug's prescriber and, if stated in the prescription, the name of the patient.

(4) The directions for use and cautionary statements, if any, contained in the prescription.

This exemption does not apply to any drugs dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to a drug dispensed in violation of subsection (a), (b), (c), or (d).

(f) The state department may adopt rules to remove drugs subject to section 4(4) of this chapter, section 7 of this chapter, or section 8 of this chapter from the requirements of subsections (a) through (d) when the requirements are not necessary for the protection of public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued under the Federal Act may also, by rules adopted by the state department, be removed from the requirement of subsections (a) through (d).

(g) A drug that is subject to subsections (a) through (d) is considered to be misbranded if at any time before dispensing the drug's label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which subsections (a) through (d) does not apply is considered to be misbranded if, at any time before dispensing, the drug's label bears the caution statement described in this subsection.

(h) This section does not relieve a person from a requirement prescribed by or under authority of law with respect to drugs included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

As added by P.L.2-1993, SEC.25. Amended by P.L.144-1996, SEC.12.

IC 16-42-3-7

Sec. 7. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) A person may not sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce any new drug unless:

(1) an application to sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce a new drug has been approved and the approval has not been withdrawn under Section 505 of the Federal Act; or

(2) if not subject to the Federal Act the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling of the drug.

(c) Before selling or offering for sale the new drug, there must be filed with the state department an application setting forth the following:

(1) Full reports of investigations that have been made to show whether or not the drug is safe for use and whether the drug is effective in use.

(2) A full list of the articles used as components of the drug.

(3) A full statement of the composition of the drug.

(4) A full description of the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drug.

(5) Such samples of the drug and of the articles used as components of the drug that the state department requires.

(6) Specimens of the labeling proposed to be used for the drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-8

Sec. 8. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) An application provided for under section 7 of this chapter becomes effective on the one hundred eightieth day after the filing of the application. However, if the state department finds, after due notice to the applicant and giving the applicant an opportunity for a hearing that:

(1) the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling of the drug;

(2) the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drugs are inadequate to preserve the drug's identity, strength, quality, and purity; or

(3) based on a fair evaluation of all material facts, that the labeling is false or misleading in any particular;

the state department shall, before the effective date of the application, issue an order refusing to permit the application to become effective.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-9

Sec. 9. (a) Sections 7 and 8 of this chapter do not apply to the following:

(1) To a drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail) if the physician, dentist, or veterinarian is licensed by law to administer the drug, and the drug bears a label containing the name and place of business of the dispenser, the serial number and date of the prescription, and the name of the physician, dentist, or veterinarian.

(2) To a drug exempted by rule of the state department and that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs.

(3) To a drug sold in Indiana or introduced into intrastate commerce at any time before the enactment of the Federal Act, if the drug's labeling contained the same representations concerning the conditions of the drug's use.

(4) To any drug that is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the Animal Virus-Serum Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.).

(5) To a drug subject to section 4(10) of this chapter.

(b) Rules exempting drugs intended for investigational use under subsection (a)(2) may, within the discretion of the state department among other conditions relating to the protection of the public health, provide for conditioning the exemption upon the following:

(1) The submission to the state department, before any clinical testing of a new drug is undertaken, of reports by the manufacturer or the sponsor of the investigation of the drug or preclinical tests, including tests on animals, of the drug adequate to justify the proposed clinical testing.

(2) The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of the investigators that patients to whom the drug is administered will be under the manufacturer's or sponsor's personal supervision or under the supervision of investigators responsible to the manufacturer or sponsor and that the manufacturer or sponsor will not supply the drug to any other investigator or to clinics for administration to human beings.

(3) The establishment and maintenance of the records and the making of the reports to the state department by the manufacturer or the sponsor of the investigation of the drug of data (including analytical reports by investigators) obtained as the result of the investigational use of the drug that the state department finds will enable the state department to evaluate the safety and effectiveness of the drug if an application is filed under section 8 of this chapter.

(c) Rules exempting drugs intended for investigational use under subsection (a)(2) must provide that the exemption is conditioned upon the manufacturer or the sponsor of the investigation requiring that experts using the drugs for investigational purposes certify to the manufacturer or sponsor that the experts will inform any human beings to whom the drugs or any controls used in connection with the drugs are being administered that the drugs are being used for investigational purposes and will obtain the consent of the human beings or their representatives, except where they consider it not feasible or, in their

professional judgment, contrary to the best interests of the human beings.

(d) This section does not require a clinical investigator to submit directly to the state department reports on the investigational use of drugs. The regulations adopted under Section 505(i) of the Federal Act are the rules in Indiana. The state may adopt rules, whether or not in accordance with regulations promulgated under the Federal Act.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-10

Sec. 10. (a) An order refusing to permit an application under section 7 or 8 of this chapter to become effective may be revoked by the state department.

(b) The state department may, after affording an opportunity for public hearing and judicial appeal, revoke an application approved under section 7 or 8 of this chapter if the state department finds any of the following:

(1) That the drug, based on evidence acquired after approval, may not be safe or effective for the intended use.

(2) That the facilities or controls used in the manufacture, processing, or labeling of the drug may present a hazard to the public health.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-11

Sec. 11. The representation of a drug in the labeling or advertisement as an antiseptic is considered to be a representation that the drug is a germicide, except if a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involves prolonged contact with the body.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-12

Sec. 12. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

As added by P.L.2-1993, SEC.25.

End of section.

IC 16-42-19

Chapter 19. Drugs: Indiana Legend Drug Act

IC 16-42-19-1

Sec. 1. This chapter is intended to supplement IC 16-42-1 through IC 16-42-4.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-2

Sec. 2. As used in this chapter, "drug" means the following:

(1) Articles or substances recognized in United States Pharmacopeial Convention, Inc.; The United States Pharmacopeia, Twenty-Second Edition (1990) or United States Pharmacopeial Convention, Inc.; The National Formulary, Seventeenth Edition (1990) as revised by United States Pharmacopeial Convention, Inc.; Supplement 1 to The United States Pharmacopeia, Twenty-Second Edition and The National Formulary, Seventeenth Edition (1990); and any supplements printed after 1990.

(2) Articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(3) Articles other than food intended to affect the structure or any function of the body of human beings or other animals.

(4) Articles intended for use as a component of any article specified in subdivision (1), (2), or (3).

(5) Devices.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.1.

IC 16-42-19-3

Sec. 3. As used in this chapter, "drug order" means an order that meets the following conditions:

(1) Is:

(A) a written order in a hospital or other health care institution for an ultimate user for a drug or device, issued and signed by a practitioner; or

(B) an order transmitted by other means of communication from a practitioner that is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution.

(2) Contains the following:

(A) The name and bed number of the patient.

(B) The name and strength or size of the drug or device.

(C) Unless specified by individual institutional policy or guidelines, the amount to be dispensed either in quantity or days.

(D) Adequate directions for the proper use of the drug or device when administered to the patient.

(E) The name of the prescriber.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-4

Sec. 4. As used in this chapter, "investigational or new drug" means a drug that is limited by state law to use under professional supervision of a practitioner authorized by law to prescribe or administer the drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-5

Sec. 5. As used in this chapter, "practitioner" means any of the following:

(1) A licensed physician.

(2) A veterinarian licensed to practice veterinary medicine in Indiana.

(3) A dentist licensed to practice dentistry in Indiana.

(4) A podiatrist licensed to practice podiatric medicine in Indiana.

(5) An optometrist who is:

(A) licensed to practice optometry in Indiana; and

(B) certified under IC 25-26-15.

(6) An advanced practice nurse who meets the requirements of IC 25-23-1-19.5.

As added by P.L.2-1993, SEC.25. Amended by P.L.185-1993, SEC.1.

IC 16-42-19-6

Sec. 6. As used in this chapter, "precursor" means a substance, other than a legend drug, that:

(1) is an immediate chemical intermediate that can be processed or synthesized into a legend drug; and

(2) is used or produced primarily for use in the manufacture of a legend drug by persons other than persons:

(A) licensed to manufacture the legend drug by the Indiana board of pharmacy;

(B) registered by the state department; or

(C) licensed to practice pharmacy by the Indiana board of pharmacy.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-7

Sec. 7. As used in this chapter, "prescription" means:

(1) a written order to or for an ultimate user for a drug or device containing the name and address of the patient, the name and strength or size of the drug or device, the amount to be dispensed, adequate directions for the proper use of the drug or device by the patient, and the name of the practitioner, issued and signed by a practitioner; or

(2) an order transmitted by other means of communication from a practitioner that is immediately reduced to writing by the pharmacist.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-8

Sec. 8. As used in this chapter, "sale" means every sale and includes the following:

(1) Manufacturing, processing, transporting, handling, packing, or any other production, preparation, or repackaging.

(2) Exposure, offer, or any other proffer.

(3) Holding, storing, or any other possession.

(4) Dispensing, giving, delivering, or any other supplying.

(5) Applying, administering, or any other using.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-9

Sec. 9. As used in this chapter, "warehouseman" means a person who stores legend drugs for others and who has no control over the disposition of legend drugs except for the purpose of storage.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-10

Sec. 10. As used in this chapter, "wholesaler" means a person engaged in the business of distributing legend drugs that the person has not produced or prepared to persons included in any of the classes named in section 21 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-11

Sec. 11. (a) Except as provided in section 21 of this chapter, a person may not sell a legend drug unless either of the following conditions exist:

(1) Except as provided in subsection (b), the legend drug is dispensed by a pharmacist upon an original prescription or drug order with the drug product specified on the prescription or drug order or by the authorization of the practitioner and there is affixed to the immediate container in which the drug is delivered a label bearing the following:

(A) The name, address, and phone number of the establishment from which the drug was dispensed.

(B) The date on which the prescription for the drug was filled.

(C) The number of the prescription as filed in the prescription files of the pharmacist who filled the prescription.

(D) The name of the practitioner who prescribed the drug.

(E) The name of the patient, or if the drug was prescribed for an animal, a statement of the species of the animal.

(F) The directions for the use of the drug as contained in the prescription.

(2) The legend drug is delivered by the practitioner in good faith in the course of practice and the immediate container in which the drug is delivered bears a label on which appears the following:

(A) The directions for use of the drug.

(B) The name and address of the practitioner.

(C) The name of the patient.

(D) If the drug is prescribed for an animal, a statement of the species of the animal.

This section does not prohibit a practitioner from delivering professional samples of legend drugs in their original containers in the course of the practitioner's practice when oral directions for use are given at the time of delivery.

(b) Notwithstanding subsection (a)(1), the following apply:

(1) A pharmacist at a hospital licensed under IC 16-21 may fill a drug order for a legend drug with a drug product allowed under the hospital's policies and procedures for the use, selection, and procurement of drugs.

(2) A pharmacist who fills a prescription for a legend drug must comply with IC 16-42-22 and IC 25-26-16.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.2.

IC 16-42-19-12

Sec. 12. Except as authorized under IC 25-26-13-25(c), a person may not refill a prescription or drug order for a legend drug except in the manner designated on the prescription or drug order or by the authorization of the practitioner.

As added by P.L.2-1993, SEC.25. Amended by P.L.270-2001, SEC.1.

IC 16-42-19-13

Sec. 13. A person may not possess or use a legend drug or a precursor unless the person obtains the drug:

(1) on the prescription or drug order of a practitioner; or

(2) in accordance with section 11(2) or 21 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-14

Sec. 14. A person may not fail to keep records as required by section 22 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-15

Sec. 15. A person may not refuse to make available and to accord full opportunity to check a record, as required by section 22 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-16

Sec. 16. A person may not do any of the following:

(1) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug by any of the following:

(A) Fraud, deceit, misrepresentation, or subterfuge.

(B) The forgery or alteration of a prescription, drug order, or written order.

(C) The concealment of a material fact.

(D) The use of a false name or the giving of a false address.

(2) Communicate information to a physician in an effort unlawfully to procure a legend drug or unlawfully to procure the administration of a legend drug. Such a communication is not considered a privileged communication.

(3) Intentionally make a false statement in a prescription, drug order, order, report, or record required by this chapter.

(4) For the purpose of obtaining a legend drug, falsely assume the title of or represent oneself to be a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, or other person.

(5) Make or utter a false or forged prescription or false drug order or forged written order.

(6) Affix a false or forged label to a package or receptacle containing legend drugs. This subdivision does not apply to law enforcement agencies or their representatives while engaged in enforcing this chapter.

(7) Dispense a legend drug except as provided in this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.3.

IC 16-42-19-17

Sec. 17. A person may not possess or have under the person's control with intent to violate this chapter an instrument or contrivance designed or generally used in smoking a legend drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-18

Sec. 18. A person may not possess or have under control with intent to violate this chapter a hypodermic syringe or needle or an instrument adapted for the use of a legend drug by injection in a human being.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-19

Sec. 19. Except as provided in section 21 of this chapter, a person may not possess or use an anabolic steroid without a valid prescription or drug order issued by a practitioner acting in the usual course of the practitioner's professional practice.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-20

Sec. 20. (a) A prescription or drug order for a legend drug is not valid unless the prescription or drug order is issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's business.

(b) A practitioner may not knowingly issue an invalid prescription or drug order for a legend drug.

(c) A pharmacist may not knowingly fill an invalid prescription or drug order for a legend drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-21

Sec. 21. Sections 11, 13, 19, and 25(b) of this chapter are not applicable to the following:

(1) The sale of legend drugs to persons included in any of the classes named in subdivision (2), or to the agents or employees of such persons for use in the usual course of their business or practice or in the performance of their official duties.

(2) Possession of legend drugs by the following persons or their agents or employees for such use:

(A) Pharmacists.

(B) Practitioners.

(C) Persons who procure legend drugs for handling by or under the supervision of pharmacists or practitioners employed by them or for the purpose of lawful research, teaching, or testing and not for resale.

(D) Hospitals and other institutions that procure legend drugs for lawful administration by practitioners.

(E) Manufacturers and wholesalers.

(F) Carriers and warehousemen.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-22

Sec. 22. (a) Manufacturers and wholesalers shall maintain records of the movement in commerce of legend drugs for two (2) years immediately following the date of the last entry on those records and shall make those records available, at reasonable times, to law enforcement agencies and their representatives in the enforcement of this chapter.

(b) Evidence obtained under this section may not be used in a

criminal prosecution of the person from whom obtained.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-23

Sec. 23. (a) As used in this section, "mechanical device" means a machine for storage and dispensing of drugs. The term does not include devices or instruments used by practitioners in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(b) A person may not maintain, operate, or use any type of mechanical device in which any legend drug or narcotic drug is stored or held for the purpose of dispensing the drug from the mechanical device. However, the mechanical device may be used for the storage and dispensing of legend drugs if:

(1) the mechanical device is located on the premises of a business or establishment holding a valid pharmacy permit issued by the Indiana board of pharmacy; and

(2) the mechanical device is operated under the direct supervision and control of a registered pharmacist.

(c) Inspectors of the Indiana board of pharmacy may inspect the premises of any person suspected of violating this section.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-24

Sec. 24. (a) A store, shop, warehouse, dwelling house, apartment, building, vehicle, boat, aircraft, or any other place that is used:

(1) by a person for the purpose of unlawfully using a legend drug; or

(2) for the unlawful keeping or selling of the legend drug;

is a common nuisance.

(b) A person may not:

(1) keep or maintain a common nuisance; or

(2) frequent or visit a place knowing the place to be used for a purpose;

as described in subsection (a).
As added by P.L.2-1993, SEC.25.

IC 16-42-19-25

Sec. 25. (a) A practitioner may not prescribe, order, distribute, supply, or sell an anabolic steroid for any of the following:

(1) Enhancing performance in an exercise, sport, or game.

(2) Hormonal manipulation intended to increase muscle mass, strength, or weight without a medical necessity.

(b) Except as provided in section 21 of this chapter, a person who is not a practitioner or lawful manufacturer of anabolic steroids may not do any of the following:

(1) Knowingly or intentionally manufacture or deliver an anabolic steroid, pure or adulterated.

(2) Possess, with intent to manufacture or deliver, an anabolic steroid.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-26

Sec. 26. In:

(1) any complaint, information, affidavit, or indictment; and

(2) any action or proceeding brought for the enforcement of any provision of this chapter;

it is not necessary to negate an exception, excuse, proviso, or exemption contained in this chapter. The burden of proof of such an exception, excuse, proviso, or exemption is upon the defendant.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-27

Sec. 27. (a) A person who knowingly violates this chapter, except sections 24 and 25(c) of this chapter, commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction under this subsection or IC 16-6-8-10(a) before its repeal.

(b) A person who violates section 24 of this chapter commits a Class B misdemeanor.

(c) A person who violates section 25(b) of this chapter commits dealing in an anabolic steroid, a Class C felony. However, the offense is a Class B felony if the person delivered the anabolic steroid to a person who is:

(1) less than eighteen (18) years of age; and

(2) at least three (3) years younger than the delivering person.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-28

Sec. 28. Law enforcement officers in the performance of their official duties are exempt from prosecution for and may not be convicted of violations of this chapter.
As added by P.L.2-1993, SEC.25.

End of section.

ARTICLE 5. PRESCRIPTIVE AUTHORITY FOR ADVANCED PRACTICE NURSING

Rule 1. Prescriptive Authority

848 IAC 5-1-1 Initial authority to prescribe legend drugs
Authority: IC 25-23-1-7
Affected: IC 25-23-1

Sec. 1. (a) An advanced practice nurse may be authorized to prescribe legend drugs, including controlled substances, if the advanced practice nurse does the following:

(1) Submits an application on a form prescribed by the board with the required fee, including, but not limited to, the following information:

(A) Complete name, residence and office addresses with zip codes, and residence and business telephone numbers with area codes.

(B) All names used by the applicant, explaining the reasons for any name change or use.

(C) Date and place of birth.

(D) Citizenship and visa status, if applicable.

(E) A complete statement of all nursing education received, providing:

(i) names and locations of all colleges, schools, or universities attended;

(ii) dates of attendance; and

(iii) degrees obtained or received.

(F) Whether the applicant has ever had any disciplinary action taken against the applicant's nursing license by the board or by the licensing agency of any other state or jurisdiction and the details and dates thereof.

(G) A complete list of all places of employment, including:

(i) the names and addresses of employers;

(ii) the dates of each employment; and

(iii) employment responsibilities held or performed which the applicant had since graduation from nursing school.

(H) Whether the applicant is, or has been, addicted to any narcotic drug, alcohol, or other drugs and, if so, the details thereof.

(I) Whether the applicant has been convicted of any violation of law relating to drug abuse, controlled substances, narcotic drugs, or any other drugs.

(J) Whether the applicant has previously been licensed to practice nursing in any other state or jurisdiction and, if so:

(i) the names of such states or jurisdictions which previously licensed the applicant;

(ii) the dates of such licensure;

(iii) the license number; and

(iv) the current status of such licensure.

(K) Whether the applicant has been denied a license to practice nursing by any state or jurisdiction and, if so, the details thereof, including:

(i) the name and location of the state or jurisdiction denying licensure;

(ii) the date of denial of such licensure; and

(iii) the reasons relating thereto.

(L) A certified statement that the applicant has not been convicted of a criminal offense (excluding minor traffic violations), or a certified statement listing all criminal offenses of which the applicant has been convicted. This listing must include:

(i) the offense of which the applicant was convicted;

(ii) the court in which the applicant was convicted; and

(iii) the cause number in which the applicant was convicted.

(M) All information in the application shall be submitted under oath or affirmation, subject to the penalties for perjury.

(2) Submits proof of an active, unrestricted Indiana registered nurse license.

(3) Submits proof of having met the requirements of all applicable laws for practice as an advanced practice nurse in the state of Indiana.

(4) Submits proof of a baccalaureate or higher degree in nursing.

(5) Submits proof of having successfully completed a graduate level pharmacology course, consisting of at least two (2) semester hours of academic credit from a college or university accredited by the Commission on Recognition of Postsecondary Accreditation:

(A) within five (5) years of the date of application; or

(B) as part of a degree program, with clear and convincing proof of subsequent collaborative experience as an advanced practice nurse within the last five (5) years, if the course was completed more than five (5) years, but not more than eight (8) years, prior to the date of application.

(6) Submits proof of collaboration with a licensed practitioner, in the form of a written practice agreement that sets forth the manner in which the advanced practice nurse and licensed practitioner will cooperate, coordinate, and consult with each other in the provision of health care to patients. Practice agreements shall be in writing and shall also set forth provisions for the type of collaboration between the advanced practice nurse and the licensed practitioner, and the reasonable and timely review by the licensed practitioner of the prescribing practices of the advanced practice nurse. Specifically, the written practice agreement shall contain at least the following information:

(A) Complete names, home and business addresses, zip codes, and telephone numbers of the licensed practitioner and the advanced practice nurse.

(B) A list of all other offices or locations besides those listed in clause (A) where the licensed practitioner authorized the advanced practice nurse to prescribe.

(C) All specialty or board certifications of the licensed practitioner and the advanced practice nurse.

(D) The specific manner of collaboration between the licensed practitioner and the advanced practice nurse, including how the licensed practitioner and the advanced practice nurse will:

(i) work together;

(ii) share practice trends and responsibilities;

(iii) maintain geographic proximity; and

(iv) provide coverage during absence, incapacity, infirmity, or emergency by the licensed practitioner.

(E) A description of what limitation, if any, the licensed practitioner has placed on the advanced practice nurse's prescriptive authority.

(F) A description of the time and manner of the licensed practitioner's review of the advanced practice nurse's prescribing practices. The description shall include provisions that the advanced practice nurse must submit documentation of the advanced practice nurse's prescribing practices to the licensed practitioner within seven (7) days. Documentation of prescribing practices shall include, but not be limited to, at least a five percent (5%) random sampling of the charts and medications prescribed for patients.

(G) A list of all other written practice agreements of the licensed practitioner and the advanced practice nurse.

(H) The duration of the written practice agreement between the licensed practitioner and the advanced practice nurse.

(7) Written practice agreements for advanced practice nurses applying for prescriptive authority shall not be valid until prescriptive authority is granted by the board.

(b) When the board determines that the applicant has met the requirements under subsection (a), the board shall send written notification of authority to prescribe to the advanced practice nurse, including the identification number and designated authorized initials to be used by the advanced practice nurse.

(c) Advanced practice nurses who have been granted prescriptive authority will immediately notify the board in writing of any changes in, or termination of, written practice agreements, including any changes in the prescriptive authority of the collaborating licensed practitioner. Written practice agreements shall terminate automatically if the advanced practice nurse or licensed practitioner no longer has an active, unrestricted license.

(d) Advanced practice nurses wishing to prescribe controlled substances must obtain an Indiana controlled substances registration and a federal Drug Enforcement Administration registration. (Indiana State Board of Nursing; 848 IAC 5-1-1; filed Jul 29, 1994, 5:00 p.m.: 17 IR 2876; readopted filed Nov 6, 2001, 4:18 p.m.: 25 IR 939)

848 IAC 5-1-2 Prescribing legend drugs; use of forms (Repealed)

Sec. 2. (Repealed by Indiana State Board of Nursing; filed Dec 19, 1996, 10:00 a.m.: 20 IR 1122)

848 IAC 5-1-3 Renewal of authority to prescribe legend drugs

Authority: IC 25-23-1-7
Affected: IC 25-23-1

Sec. 3. (a) Prescriptive authority for the advanced practice nurse expires on October 31 in each odd-numbered year. Failure to renew the prescriptive authority on or before the expiration date will automatically render the authority invalid without any action by the board.

(b) An application form and instructions for renewal of the authority to prescribe legend drugs will be mailed in odd-numbered years with the renewal for registered nurse licensure.

(c) Applicants for renewal of the prescriptive authority shall pay a renewal fee in addition to the fee for renewal of the registered nurse license.

(d) Applications for renewal of the prescriptive authority shall be mailed to the last known address of the licensee. Failure to receive the application for renewal shall not relieve the licensee of the responsibility for renewing the registered nurse license and the authorization to prescribe by the renewal date.

(e) Applicants for renewal of prescriptive authority shall submit to the board along with the renewal form and fee proof of at least thirty (30) actual contact hours of continuing education during the two (2) years immediately preceding renewal, including at least eight (8) actual contact hours of pharmacology, approved by a nationally approved sponsor of continuing education for nurses and approved by the board and contained on a list at the health professions bureau. (Indiana State Board of Nursing; 848 IAC 5-1-3; filed Jul 29, 1994, 5:00 p.m.: 17 IR 2878; readopted filed Nov 6, 2001, 4:18 p.m.: 25 IR 939)

Rule 2. Limitations of Rules

848 IAC 5-2-1 Limitations of rules

Authority: IC 25-23-1-7
Affected: IC 25-23-1

Sec. 1. No written practice agreement shall be necessary unless the advanced practice nurse seeks prescriptive authority. (Indiana State Board of Nursing; 848 IAC 5-2-1; filed Jul 29, 1994, 5:00 p.m.: 17 IR 2878; readopted filed Nov 21, 2001, 10:23 a.m.: 25 IR 1329)

Rule 3. Fees for Prescriptive Authority

848 IAC 5-3-1 Fees for prescriptive authority

Authority: IC 25-23-1-7
Affected: IC 25-23-1

Sec. 1. (a) The application fee for an advanced practice nurse to receive prescriptive authority shall be fifty dollars ($50).

(b) The fee for renewal of advanced practice nurse prescriptive authority shall be ten dollars ($10).

(c) The penalty fee for late renewals is as established by the health professions bureau.

(d) The fee for a duplicate wall certificate for advanced practice nurse prescriptive authority shall be ten dollars ($10).

(e) The fee for written verification of advanced practice nurse prescriptive authority shall be ten dollars ($10). (Indiana State Board of Nursing; 848 IAC 5-3-1; filed Jul 29, 1994, 5:00 p.m.: 17 IR 2879; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3105; readopted filed Jul 30, 2001, 2:07 p.m.: 24 IR 4237)

End of section.

IC 25-26-15

Chapter 15. Indiana Optometric Legend Drug Prescription Advisory Committee

IC 25-26-15-1

Sec. 1. As used in this chapter, "associated structures of the eye" means the:

(1) eyelids;
(2) eyebrows;
(3) conjunctiva;
(4) lachrymal apparatus; and
(5) orbital tissues.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-2

Sec. 2. As used in this chapter, "administer" means the direct application of a legend drug by an optometrist to a patient.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-3

Sec. 3. As used in this chapter, "board" means the Indiana board of pharmacy established under IC 25-26-13-3.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-4

Sec. 4. As used in this chapter, "committee" refers to the optometric legend drug prescription advisory committee established under section 12 of this chapter.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-5

Sec. 5. As used in this chapter, "diagnostic legend drug" means a pharmacological agent approved by the committee that is used in the examination of the human eye for the purpose of detecting abnormalities.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-6

Sec. 6. As used in this chapter, "dispense" means to deliver a legend drug to an ultimate user by or pursuant to a lawful order of an optometrist. The term includes the:

(1) prescribing;
(2) administering;
(3) packaging;
(4) labeling; or
(5) compounding;

necessary to prepare the drug for delivery.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-7

Sec. 7. As used in this chapter, "legend drug" has the meaning set forth in IC 16-18-2-199. The term does not include controlled substances as defined in IC 35-48-1.

As added by P.L.147-1991, SEC.7. Amended by P.L.2-1993, SEC.148.

IC 25-26-15-8

Sec. 8. As used in this chapter, "optometrist" means a person licensed as an optometrist under IC 25-24-1.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-9

Sec. 9. As used in this chapter, "person" means an individual.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-10

Sec. 10. As used in this chapter, "prescription" means a written order, or an order transmitted by other means of communication that is immediately reduced to writing by the pharmacist, from an optometrist to or for an ultimate user for a drug or device, containing:

(1) the name and address of the patient;
(2) the date of issue;
(3) the name and strength or size (if applicable) of the drug or device;
(4) the amount to be dispensed (unless indicated by directions and duration of therapy);
(5) adequate directions for the proper use of the drug or device by the patient;
(6) the name and certification number of the prescribing optometrist; and
(7) the signature of the optometrist if the prescription is in written form.

As added by P.L.147-1991, SEC.7. Amended by P.L.288-2001, SEC.5.

IC 25-26-15-11

Sec. 11. As used in this chapter, "therapeutic legend drug" means a pharmacological agent that is used in the treatment of a diagnosed condition of the:

(1) human eye; or
(2) associated structures of the human eye.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-12

Sec. 12. (a) The Indiana optometric legend drug prescription advisory committee is established.

(b) The committee consists of five (5) members as follows:

(1) One (1) optometrist appointed by the Indiana optometry board from among its members.
(2) One (1) optometrist who is:
(A) appointed by the governor; and
(B) holds a license to practice optometry in Indiana.
(3) One (1) pharmacist appointed by the board from among its members.
(4) One (1) physician who is:
(A) trained in the diagnosis and treatment of diseases of the eye;
(B) appointed by the governor; and
(C) hold an unlimited license to practice medicine in Indiana.

The physician may be a member of the medical licensing board.

(5) One (1) pharmacologist who is:
(A) appointed by the governor; and
(B) actively engaged in teaching pharmacology at a higher education institution (as defined under IC 20-12-5.5-1) or a private institution of higher education (as defined under IC 20-12-63-3).

(c) A member of the committee appointed by a board serves a one (1) year term. A member appointed by the governor serves a four (4) year term.

(d) A member of the committee may be removed for cause by the appointing authority.

(e) If a vacancy occurs on the committee, the authority appointing the vacating member shall appoint a successor to serve the unexpired term of the vacating member.

(f) The committee shall annually elect from its members the following:

(1) One (1) member to serve as chairman of the committee.
(2) One (1) member to serve as secretary of the committee.

(g) No member shall serve consecutive terms as chairman of the committee. The chairman may not be succeeded as chairman by a member of the same profession.

(h) The secretary of the committee shall call a meeting of the committee upon the request of the chairman or the written request of two (2) members.

(i) A meeting of the committee may be conducted at any time and at any place in Indiana convenient for conducting the business of the committee. Sufficient advance notice of each committee meeting must be given to allow all members to attend, unless notice of the meeting is

waived in writing by all of the committee members.

(j) Each member of the committee who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). Each member of the committee is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the Indiana department of administration and approved by the budget agency.

(k) Three (3) members of the committee constitute a quorum.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-13

Sec. 13. The committee shall do the following:

(1) Adopt rules under IC 4-22-2 to do the following:

(A) Establish a formulary of legend drugs that may be prescribed, dispensed, or administered by an optometrist.

(B) Set fees described in IC 25-1-8.

(C) Carry out this chapter.

(2) Establish education and training requirements in ocular pharmacology required for certification to do the following:

(A) Administer therapeutic legend drugs.

(B) Dispense legend drugs.

(C) Prescribe legend drugs.

(3) Establish continuing education requirements for renewal of the certificate issued under this chapter.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-14

Sec. 14. (a) The formulary established under section 13 of this chapter shall include legend drugs that:

(1) may be independently prescribed by an optometrist; or

(2) must be dependently prescribed by an optometrist.

(b) If a legend drug is designated in the formulary as one (1) that must be dependently prescribed, the formulary must designate:

(1) those legend drugs for which the optometrist must only notify the patient's physician that the optometrist is prescribing the legend drug; and

(2) those legend drugs for which the optometrist must consult with the patient's physician prior to the prescribing the legend drug.

(c) If the patient has no physician, the optometrist must document such in the patient's file.

(d) If the legend drug is designated in the formulary as a legend drug that must be dependently prescribed, the optometrist shall indicate on the prescription that:

(1) the patient's physician has been contacted; or

(2) the patient has indicated to the optometrist that the patient has no physician.

(e) If the legend drug is designated in the formulary as a legend drug that may be independently prescribed, the optometrist may prescribe the legend drug without notifying the patient's physician.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-15

Sec. 15. Upon the recommendation of the committee, the board shall issue a certificate to a licensed optometrist who:

(1) applies; and

(2) successfully fulfills all of the requirements of this chapter.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-16

Sec. 16. An optometrist who applies for a certificate to administer, dispense, and prescribe legend drugs must meet one (1) of the following requirements:

(1) Do all of the following:

(A) Apply in the form and manner prescribed by the committee.

(B) Provide proof of education in ocular pharmacology from a school or college of optometry or medicine approved by the optometry board.

(C) Pass the Treatment and Management of Ocular Disease (TMOD) examination that is sponsored by the International Association of Boards of Examiners in Optometry (IAB) and administered by the National Board of Examiners in Optometry.

(D) Pay the fee established by the committee.

(2) Do all of the following:

(A) Apply in the form and manner prescribed by the committee.

(B) Pay the fee established by the committee.

(C) Provide proof that the applicant has obtained twenty (20) hours of continuing education in ocular pharmacology after January 1, 1991.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-17

Sec. 17. An applicant must hold a license to practice optometry in order to hold a certificate.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-18

Sec. 18. The board shall renew a certificate issued under this chapter:

(1) concurrently with the renewal of the optometrist's license to practice optometry;

(2) upon payment of the renewal fee set by the committee; and

(3) upon completion of continuing education requirements established under section 13 of this chapter.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-19

Sec. 19. (a) Optometrists may administer topical diagnostic legend drugs limited to:

(1) miotics;

(2) mydriatics;

(3) anesthetics; and

(4) cycloplegics;

without holding a certificate issued under this chapter. These pharmaceutical agents may be applied in diagnostic procedures only as a part of an examination of the eye.

(b) The board may authorize optometrists holding a certificate issued under this chapter to:

(1) administer for therapeutic use;

(2) dispense; or

(3) prescribe;

legend drugs that are included in the formulary established by the committee under section 13 of this chapter, in the treatment of any condition of the eye or the associated structures of the eye.

As added by P.L.147-1991, SEC.7.

IC 25-26-15-20

Sec. 20. (a) An optometrist may not:

(1) administer, dispense, or prescribe therapeutic legend drugs; or

(2) dispense or prescribe diagnostic legend drugs;

unless the optometrist is certified under this chapter.

(b) An optometrist may administer diagnostic legend drugs without obtaining a certificate under this chapter.

(c) A person who violates this chapter commits a Class A misdemeanor.

As added by P.L.147-1991, SEC.7.

End of section.

TITLE 857 INDIANA OPTOMETRIC LEGEND DRUG PRESCRIPTION ADVISORY COMMITTEE

ARTICLE 1. CERTIFICATION

Rule 1. Definitions

857 IAC 1-1-1 Definitions
Authority: IC 25-26-15-13
Affected: IC 25-26-15

Sec. 1. (a) All terms which are defined in IC 25-26-15 shall have the same meaning as they are so defined when used in this title.

(b) The definitions in this rule apply throughout this title. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-1-1; filed May 15, 1992, 5:00 p.m.: 15 IR 2249; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 1-1-2 "Bureau" defined
Authority: IC 25-26-15-13
Affected: IC 25-1-5-3; IC 25-26-15

Sec. 2. "Bureau" refers to the health professions bureau established under IC 25-1-5-3. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-1-2; filed May 15, 1992, 5:00 p.m.: 15 IR 2249; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

Rule 2. Continuing Education

857 IAC 1-2-1 Scope of rule
Authority: IC 25-26-15-13
Affected: IC 25-26-15-16; IC 25-26-15-18

Sec. 1. This rule establishes the requirements for continuing education both to obtain an Indiana optometric legend drug certificate under IC 25-26-15-16(2) and to renew a certificate under IC 25-26-15-18. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-2-1; filed May 15, 1992, 5:00 p.m.: 15 IR 2249; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 1-2-2 Course approval
Authority: IC 25-26-15-13
Affected: IC 25-26-15-16; IC 25-26-15-18

Sec. 2. (a) The sponsoring organization must file an application provided by the bureau for course work in ocular pharmacology. The application shall include the following:

(1) Name of lecturer.
(2) Academic and professional background of lecturer.
(3) Brief summary of content of program.
(4) Date and location of program.
(5) Number of clock hours of continuing education requested.
(6) Name of the person who will monitor attendance and the manner in which attendance will be monitored.
(7) Any other pertinent information required by the committee.

(b) As a condition to approval of programs, the sponsoring organization must agree to provide participants with a record of attendance and to retain records of attendance by participants for four (4) years from the date of the program. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-2-2; filed May 15, 1992, 5:00 p.m.: 15 IR 2249; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 1-2-3 Standards for approval; length of approval time
Authority: IC 25-26-15-13
Affected: IC 25-26-15-16; IC 25-26-15-18

Sec. 3. (a) The committee will approve a course if it determines that the course will make a significant contribution to the professional knowledge of optometrists in their understanding of ocular pharmacology. In determining if a course meets this section, the committee will consider the following:

(1) The course has substantial content.
(2) The course content directly relates to ocular pharmacology or ocular therapeutics.
(3) Each faculty member who has teaching responsibility in the course is qualified by academic work or practical experience to teach the assigned subject.
(4) The physical setting for the course is suitable.
(5) High quality written materials, including notes and outlines, are available to all optometrists who enroll at, or prior to, the time the course is offered.
(6) The course is of sufficient length to provide a substantial educational experience. Courses of less than one (1) hour will be reviewed carefully to determine if they furnish a substantial educational experience.
(7) Appropriate educational methodology is used, including, but not limited to, the following:
(A) Prepared library packages.
(B) Courses of programmed instruction.
(C) Active participation and demonstration.
(D) Audio-visual materials.
(E) Workshops with live presentations of clinical cases.
(8) An adequate number of instructors is provided for the course. If audio-visual tapes are used as teaching materials, live presentations or discussion leaders must accompany the replaying of the tapes.

(b) Once a course is approved under this section, the course is approved for four (4) years from the date of initial approval if the instructor remains the same and the course content remains essentially the same in substance. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-2-3; filed May 15, 1992, 5:00 p.m.: 15 IR 2250; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1098; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

Rule 3. Application and Renewal of the Indiana Optometric Legend Drug Certificate

857 IAC 1-3-1 Applicability
Authority: IC 25-26-15-13
Affected: IC 25-26-15

Sec. 1. This rule establishes the requirements concerning applications and fees for the issuance or renewal of certificates for optometrists to administer, dispense, and prescribe legend drugs as provided for under IC 25-26-15. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-3-1; filed May 15, 1992, 5:00 p.m.: 15 IR 2250; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 1-3-2 Original certification
Authority: IC 25-26-15-13
Affected: IC 25-26-15

Sec. 2. To obtain an original certificate, an optometrist must do all of the following:

(1) Complete an Indiana optometric legend drug certificate application which shall include the following information:
(A) Name.
(B) Business name (if applicable).
(C) Primary practice address.

(D) Indiana optometrist's license number.

(E) Signature and date.

(F) Answer whether or not any previous license or certificate held by the applicant has been surrendered, revoked, denied, or is pending action.

(2) Either:

(A) do both of the following:

(i) provide proof of education in ocular pharmacology from a school or college of optometry or medicine by providing a transcript of the course work taken by the applicant from the school or college; and

(ii) provide a score report certifying successful completion of the Treatment and Management of Ocular Disease (TMOD) examination that is sponsored by the International Association of Boards of Examiners in Optometry (IAB) and administered by the National Board of Examiners in Optometry; or

(B) provide proof that the applicant has obtained twenty (20) hours of continuing education course work in ocular pharmacology after January 1, 1991, in courses approved by the committee by providing copies of certificates proving attendance.

(Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-3-2; filed May 15, 1992, 5:00 p.m.: 15 IR 2250; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 1-3-3 Renewal of the certificate

Authority: IC 25-26-15-13

Affected: IC 25-26-15

Sec. 3. (a) A certificate issued to an optometrist under IC 25-26-15 and this title expires on April 1 of each even-numbered year. The board shall renew a certificate under this section concurrently with the license of an optometrist to practice in Indiana.

(b) To renew a certificate, the optometrist must provide proof of thirty (30) hours of continuing education course work obtained since April 1 of the previous even-numbered year in courses approved by the committee under 857 IAC 1-2.

(c) For purposes of certification renewal, courses in ocular pharmacology or ocular therapeutics are acceptable to meet the continuing education requirement.

(d) An optometrist initially certified between April 1 of even-numbered years and March 31 of the succeeding odd-numbered year shall only be required to obtain fifteen (15) hours of continuing education for the initial renewal of the certificate.

(e) An optometrist initially certified between April 1st of odd-numbered years and March 31st of the succeeding even-numbered year shall not be required to obtain continuing education for the initial renewal of the certificate.

(f) Continuing education credits obtained for the original issuance of a certificate or to complete the continuing education requirements of a previous biennium may not be counted toward meeting the continuing education requirements under subsection (b). (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-3-3; filed May 15, 1992, 5:00 p.m.: 15 IR 2250; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1098; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

Rule 4. Fees

857 IAC 1-4-1 Fees

Authority: IC 25-26-15-13

Affected: IC 25-26-15

Sec. 1. (a) An optometrist who applies for an Indiana optometric legend drug certificate under IC 25-26-15 and this title must pay a twenty dollar ($20) fee.

(b) To renew a certificate, an optometrist must pay a twenty dollar ($20) renewal fee.

(c) To restore a certificate that is expired, an optometrist must comply with subsection (b) and 857 IAC 1-3-3. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 1-4-1; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2464; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3107)

ARTICLE 2. FORMULARY OF LEGEND DRUGS

Rule 1. General Provisions

857 IAC 2-1-1 Applicability

Authority: IC 25-26-15-13

Affected: IC 25-26-15

Sec. 1. This article establishes a formulary of legend drugs that may be prescribed, dispensed, or administered by an optometrist licensed in Indiana and certified under IC 25-26-15 and this title. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-1-1; filed Jun 1, 1992, 5:00 p.m.: 15 IR 2251; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 2-1-2 Legend drugs not listed in the formulary

Authority: IC 25-26-15-13

Affected: IC 25-26-15-19

Sec. 2. All legend drugs which do not fall into the categories listed in the formulary as found in 857 IAC 2-3 are specifically excluded from use by an optometrist except for topical diagnostic legend drugs which an optometrist may administer under IC 25-26-15-19(a). (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-1-2; filed Jun 1, 1992, 5:00 p.m.: 15 IR 2251; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 2-1-3 Certified optometrists required

Authority: IC 25-26-15-13

Affected: IC 25-26-15-19

Sec. 3. Except as provided by IC 25-26-15-19(a), only an optometrist who holds a valid Indiana optometric legend drug certificate under IC 25-26-15 and this title may administer, dispense, or prescribe the legend drugs which fall into the categories listed in the formulary. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-1-3; filed Jun 1, 1992, 5:00 p.m.: 15 IR 2251; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 2-1-4 Generic names (Repealed)

Sec. 4. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-1-5 Injectable prohibition

Authority: IC 25-26-15-13

Affected: IC 25-26-15

Sec. 5. Optometrists shall not prescribe, dispense, or administer injectables by any means. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-1-5; filed Jun 1, 1992, 5:00 p.m.: 15 IR 2251; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

Rule 2. Definitions

857 IAC 2-2-1 Applicability

Authority: IC 25-26-15-13

Affected: IC 25-26-15

Sec. 1. The definitions in this rule apply throughout this article. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-2-1; filed Jun 1, 1992, 5:00 p.m.: 15 IR 2251; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 2-2-2 "Independent" defined (Repealed)

Sec. 2. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-2-3 "Notify" defined (Repealed)

Sec. 3. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-2-4 "Patient's physician" defined
Authority: IC 25-26-15-13
Affected: IC 25-26-15-14

Sec. 4. "Patient's physician", as referred to in IC 25-26-15-14, means that licensed medical physician who, as specified by the patient and in the professional judgment of the optometrist, is the most appropriate provider with whom to communicate based upon the nature of the patient's condition and the medication being utilized. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-2-4; filed Jun 1, 1992, 5:00 p.m.: 15 IR 2252; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

Rule 3. Formulary

857 IAC 2-3-1 Adrenergic agonists (Repealed)

Sec. 1. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-2 Anesthetics (Repealed)

Sec. 2. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-3 Antibacterials (Repealed)

Sec. 3. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-4 Antihistamines; mast cell stabilizers; decongestant agents (Repealed)

Sec. 4. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-5 Anti-inflammatory agents (Repealed)

Sec. 5. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-6 Antivirals (Repealed)

Sec. 6. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-7 Beta adrenergic blocking agents (Repealed)

Sec. 7. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)857 IAC 2-3-8 Carbonic anhydrase inhibitors (Repealed)

Sec. 8. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-9 Direct acting cholinergic agents (Repealed)

Sec. 9. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-10 Hyperosmotic agents (Repealed)

Sec. 10. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-11 Mydriatics and cycloplegics (Repealed)

Sec. 11. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-12 Ocular lubrication; tear testing agents (Repealed)

Sec. 12. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-13 Ophthalmic dyes (Repealed)

Sec. 13. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-14 Combination drugs (Repealed)

Sec. 14. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-15 Nonsteroidal anti-inflammatory agents (Repealed)

Sec. 15. (Repealed by Indiana Optometric Legend Drug Prescription Advisory Committee; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099)

857 IAC 2-3-16 Formulary of legend drugs listed by category
Authority: IC 25-26-15-13
Affected: IC 35-48-1

Sec.16. (a) Legend drugs that fall into the following categories are independent for treating the eye or associated structures of the eye:

(1) Topically applied drugs.
(2) Oral antihistamine drugs.
(3) Oral decongestant drugs.
(4) Oral antimicrobial drugs.

(5) Oral nonsteroidal anti-inflammatory drugs (NSAIDs).
(6) Oral antiglaucoma drugs.
(7) Oral analgesics, which may be prescribed for a period of time not to exceed five (5) days.

(b) Controlled substances as defined in IC 35-48-1 are prohibited from use by an optometrist. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-3-16; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099; filed Jun 30, 1999, 2:45 p.m.: 22 IR 3414; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

857 IAC 2-3-17 Patient's physician notification
Authority: IC 25-26-15-13
Affected: IC 25-26-15

Sec. 17. In the best interest of the patient's health, a certified optometrist who prescribes, dispenses, or administers any legend drug which falls within the categories of section 16 of this rule is encouraged to notify the patient's physician of the use of the legend drug. (Indiana Optometric Legend Drug Prescription Advisory Committee; 857 IAC 2-3-17; filed Feb 4, 1994, 5:00 p.m.: 17 IR 1099; readopted filed Apr 24, 2001, 10:21 a.m.: 24 IR 2896)

End of section.

IC 25-26-14

Chapter 14. Wholesale Legend Drug Distributors

IC 25-26-14-1

Sec. 1. This chapter applies to any individual, partnership, limited liability company, corporation, or business firm engaging in the wholesale distribution of legend drugs within Indiana.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.394.

IC 25-26-14-2

Sec. 2. As used in this chapter, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-3

Sec. 3. As used in this chapter, "blood component" means that part of blood separated by physical or mechanical means.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-4

Sec. 4. As used in this chapter, "board" refers to the Indiana board of pharmacy established under IC 25-26-13-3.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-5

Sec. 5. As used in this chapter, "drug sample" means a unit of a legend drug that is not intended to be sold and is intended to promote the sale of the drug.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-6

Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-7

Sec. 7. As used in this chapter, "legend drug" has the meaning set forth in IC 16-18-2-199. The term includes any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to 21 U.S.C. 811 through 812.

As added by P.L.182-1991, SEC.3. Amended by P.L.2-1993, SEC.147.

IC 25-26-14-8

Sec. 8. As used in this chapter, "manufacturer" means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a legend drug.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-9

Sec. 9. As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, or a corporation.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.395.

IC 25-26-14-10

Sec. 10. As used in this chapter, "sale" includes purchase, trade, or offer to sell, purchase, or trade.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-11

Sec. 11. As used in this chapter, "wholesale distribution" means distribution of legend drugs to persons other than a consumer or patient. The term does not include:

(1) a sale between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;

(3) the sale of a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale of a drug among hospitals or other health care entities that are under common control;

(5) the sale of a drug for emergency medical reasons, including transfers of legend drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;

(6) the sale of a drug or the dispensing of a drug pursuant to a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives;

(8) the sale of blood and blood components intended for transfusion;

(9) the sale of a drug by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales during any twelve (12) consecutive months; or

(10) the sale of a drug by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy.

As added by P.L.182-1991, SEC.3. Amended by P.L.33-1993, SEC.47.

IC 25-26-14-12

Sec. 12. As used in this chapter, "wholesale drug distributor" means a person engaged in wholesale distribution of legend drugs, including:

(1) manufacturers;

(2) repackers;

(3) own-label distributors;

(4) private-label distributors;

(5) jobbers;

(6) brokers;

(7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;

(8) independent wholesale drug traders; and

(9) retail and hospital pharmacies that conduct wholesale distributions.

The term does not include a common carrier or person hired solely to transport prescription drugs.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-13

Sec. 13. The board shall adopt rules under IC 4-22-2 that conform with wholesale drug distributor licensing guidelines adopted by the United States Food and Drug Administration (21 CFR 205), including rules:

(1) necessary to carry out the purposes of this chapter;

(2) that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter; and

(3) establishing reasonable fees to carry out this chapter.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-14

YAMD.1991

Sec. 14. (a) After September 14, 1992, a person may not engage in wholesale distributions of legend drugs without having a license from the board and paying any reasonable fee required by the board.

(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.

(c) The board may require a separate license for:

(1) each facility directly or indirectly owned or operated by the

same business in Indiana; or

(2) a parent entity with divisions, subsidiaries, or affiliate companies in Indiana when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.

(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.

(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the state board of tax commissioners on any wholesale drug distributor.

(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:

(1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-15

Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.

(4) The type of ownership of operation.

(5) The name of each owner and operator of the licensee, including:

(A) if an individual, the name of the individual;

(B) if a partnership, the name of each partner, and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

(D) if a limited liability company, the name of each manager and member, the name of the limited liability company, and the name of the state where organized; and

(E) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(6) The name of the person designated by the licensee as responsible for the operation of the facilities.

(b) A material change in any information in subsection (a) of this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.396.

IC 25-26-14-16

Sec. 16. In reviewing the qualifications of persons who engage in wholesale distribution of legend drugs within Indiana, the board shall consider the following factors:

(1) A conviction of the applicant relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.

(2) A felony conviction of the applicant.

(3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.

(5) Suspension or revocation by the federal or a state government of any license held by the applicant for the manufacture or distribution of any drugs, including controlled substances.

(6) Compliance with licensing requirements under previously granted licenses.

(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.

(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-17

Sec. 17. As a condition for receiving and retaining any wholesale drug distributor license issued under to this chapter, each applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards.

(2) A security system that includes:

(A) an after hours central alarm or a comparable entry detection capability;

(B) restricted premises access;

(C) adequate outside perimeter lighting; and

(D) safeguards against employee theft.

(3) A reasonable system of recordkeeping that:

(A) describes all the wholesale distributor's activities governed by this chapter for the two (2) year period after the disposition of each product; and

(B) is reasonably accessible as determined by board rules in any inspection authorized by the board.

(4) Written policies and procedures that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including:

(A) those caused by natural disaster or government emergency;

(B) inventory inaccuracies or product shipping and receiving;

(C) outdated product;

(D) appropriate disposition of returned goods; and

(E) product recalls.

(5) Sufficient inspection procedures for all incoming and outgoing product shipments.

(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-18

Sec. 18. Any applicant denied a license or renewal under this chapter has the right of review of the board's action under IC 4-21.5.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-19

Sec. 19. (a) A person authorized by the board may enter and inspect, during normal business hours, all open premises that appear to be used by a wholesale drug distributor.

(b) Wholesale drug distributors may keep records regarding purchase and sales transactions at a central location apart from the principal office of the wholesale drug distributor or the location where the drugs were stored and from which the drugs were shipped, if the records are made available for inspection within two (2) working days of a request by the board. The records may be kept in any form permissible under federal law applicable to legend recordkeeping.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-20

Sec. 20. A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-21

Sec. 21. (a) A wholesale drug distributor license expires at midnight of the renewal date specified by the health professions bureau under IC 25-1-5-4 in each even-numbered year.

(b) The board shall mail renewal application forms to each licensed wholesale drug distributor before the first day of the month before the month in which the license expires. If an application for renewal has not been filed and the required fee paid before the license expiration date, the wholesale drug distributor license shall lapse and become void.

(c) A lapsed license may be reinstated only by meeting the requirements under IC 25-1-8-6.

(d) A wholesale drug distributor may not be open for business after the license has lapsed, until the renewal is completed.

As added by P.L.182-1991, SEC.3. Amended by P.L.269-2001, SEC.26.

IC 25-26-14-22

Sec. 22. (a) The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under IC 4-21.5.

(b) After a proceeding under IC 4-21.5, the board may assess a civil penalty against a licensed wholesale drug distributor of not more than one thousand dollars ($1,000) for each occurrence. If the licensed wholesale drug distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-23

Sec. 23. A person that knowingly purchases or receives a legend drug from any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a Class A misdemeanor. A subsequent unrelated violation of this section is a Class D felony.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-24

Sec. 24. (a) Upon application by the board, a circuit or superior court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license.

(b) An action brought under this section must be commenced either in the county where the conduct occurred or is likely to occur or in the county where the defendant resides.

(c) An action brought under this section is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-25

Sec. 25. A wholesale drug distributor that fails to allow an authorized person to enter and inspect a facility as provided in section 19 of this chapter commits a Class A misdemeanor. However, the offense is a Class D felony if the person has a prior unrelated conviction for an offense under this section.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-26

Sec. 26. A person that engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Class D felony.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-27

Sec. 27. A wholesale drug distributor that fails to comply with the conditions described in section 17 of this chapter commits a Class D felony.

As added by P.L.182-1991, SEC.3.

End of section

ARTICLE 3. WHOLESALE LEGEND DRUGS

Rule 1. Definitions

856 IAC 3-1-1 Definitions
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. All terms which are defined in IC 25-26-14 shall have the same meanings as they are so defined when used in this article. (Indiana Board of Pharmacy; 856 IAC 3-1-1; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2460; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

Rule 2. Licensing and Operational Requirements

856 IAC 3-2-1 Persons required to register
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. (a) Every person who engages in wholesale drug distribution is required to obtain a wholesale drug distributor license as required by IC 25-26-14. Only persons actually engaged in such activities are required to obtain a license; related or affiliated persons who are not engaged in such activities are not required to be licensed. For example, a stockholder or parent corporation of a corporation distributing legend drugs is not required to obtain a license.

(b) A separate license is required for each facility directly or indirectly owned or operated by the same person in Indiana.

(c) For the purpose of enforcement of the licensing requirement, "facility" means one (1) building or two (2) or more buildings in close geographic proximity to each other, such as a campus. A facility shall be identified by the wholesale drug distributor as constituting a single business operation. (Indiana Board of Pharmacy; 856 IAC 3-2-1; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2460; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

856 IAC 3-2-2 Fees
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 2. (a) The fee for original licensure and biennial renewal shall be one hundred dollars ($100) for in-state applicants. The fee for original licensure and biennial renewal shall be one hundred dollars ($100) for out-of-state applicants.

(b) Licensure fees shall be paid at the time when the application for licensure or renewal of a license is filed. (Indiana Board of Pharmacy; 856 IAC 3-2-2; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3107; readopted filed Oct 17, 2001, 3:30 p.m.: 25 IR 941)

856 IAC 3-2-3 Application forms; renewal forms
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 3. (a) Applications for licensure may be obtained by writing to the Indiana Board of Pharmacy, Health Professions Bureau, 402 West Washington Street, Room 041, Indianapolis, Indiana 46204.

(b) Wholesale drug distributor licenses shall expire on September 30th of each even-numbered year. Applications for renewal shall be mailed to the licensee. (Indiana Board of Pharmacy; 856 IAC 3-2-3; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

856 IAC 3-2-4 Inspection and review of application
Authority: IC 25-26-14-13
Affected: IC 25-26-14-17; IC 25-26-14-19Sec. 4. The board may inspect, or cause to be inspected, the establishment of an applicant or licensee pursuant to IC 25-26-14-19. The board shall review the application for licensure and other information regarding an applicant to determine whether the applicable standards of IC 25-26-14-17 have been met by the applicant. (Indiana Board of Pharmacy; 856 IAC 3-2-4; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

856 IAC 3-2-5 Wholesale drug distributor license
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 5. (a) The board shall issue a wholesale drug distributor license to applicants that qualify under IC 25-26-14.

(b) The wholesale drug distributor license shall contain the name, address, and license number of the licensee, the amount of fee paid, and the expiration date of the license. The licensee shall maintain the wholesale drug distributor license in a readily retrievable manner and shall permit inspection of the license by any official, agent, or employee of the board. (Indiana Board of Pharmacy; 856 IAC 3-2-5; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

856 IAC 3-2-6 Termination of licensure; transfer of license
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14; IC 25-26-14-15

Sec. 6. (a) The license of any person shall terminate if and when such person dies or ceases legal existence. Any licensee who ceases legal existence or discontinues business shall notify the board within ten (10) days of such fact in writing.

(b) No license or any authority conferred thereby shall be assigned or otherwise transferred except to the extent allowed by IC 25-26-14-15, and then only pursuant to the written consent of the board. (Indiana Board of Pharmacy; 856 IAC 3-2-6; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

856 IAC 3-2-7 Reciprocity
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 7. (a) An out-of-state wholesale drug distributor may obtain a license on the basis of reciprocity after payment of the licensure fee provided in section 2 of this rule and upon a demonstration to the board that the distributor qualifies under IC 25-26-14-14(f).

(b) A person who possesses one (1) or more wholesale drug distributor licenses for facilities located in Indiana shall not be required to obtain a license for facilities located outside of Indiana. (Indiana Board of Pharmacy; 856 IAC 3-2-7; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

856 IAC 3-2-8 Minimum conditions for licensure, renewal, and operations
Authority: IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 8. As a condition for receipt, renewal, and retention of a license, the following minimum requirements for the storage and handling of legend drugs, and for establishment and maintenance of legend drug distribution records, by wholesale drug distributors, their officers, agents, representatives, and employees are provided:

(1) All facilities at which legend drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(A) be of suitable size and construction to facilitate cleaning maintenance and proper operations;

(B) have storage areas designed to provide sufficient lighting, ventilation, temperature, humidity control, sanitation, working space, equipment, and security measures to assure safe and secure operation of the installation;

(C) have a quarantine area for storage of legend drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in outer or secondary sealed containers that have been opened;

(D) be maintained in a clean and orderly condition; and

(E) be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Provide security as follows:

(A) All facilities used for wholesale drug distribution shall be secure from unauthorized entry. To this end, licensees who handle and store controlled substances listed in Schedule II, Schedule III, Schedule IV, and Schedule V shall assure that their facilities meet the requirements of 856 IAC 2. In addition, facilities which handle or store controlled substances also shall meet the requirements of item (v). All other licensees shall meet the following requirements:

(i) Nonscheduled legend drugs shall, at a minimum, be stored in a building of substantial construction, with walls, roof, doors, and windows made or covered by materials which render unauthorized access difficult.

(ii) All doors providing access to such buildings shall, at a minimum, be constructed of a heavy wooden core covered by a steel plate or jacket on their outer surface, or be of equivalent construction. Primary access doors shall be equipped with a five (5) pin tumbler dead bolt lock at a minimum. Secondary access doors may be secured from the inside by means of a crossbar during periods when the facility is not in operation.

(iii) All ground floor windows shall be equipped with window locks.

(iv) Facility security systems shall include a central alarm or comparable intrusion detection system which will disclose attempts at unauthorized entry during hours when the facility is closed.

(v) The outside perimeter of these facilities shall be illuminated to a degree sufficient to disclose the presence of an unauthorized person or vehicle adjacent to the exterior surfaces of the building during hours of darkness.

(vi) Licensees of these facilities shall establish and practice measures of personnel control which will assure that only those persons authorized by the management shall have access to areas of the facility wherein legend drugs are handled or stored. In addition, procedures also shall be followed which control the access of personnel authorized to enter the facility on a temporary basis to perform necessary maintenance or for other useful purposes.

(vii) Whenever practicable, facilities shall be protected, additionally, by arrangement with local law enforcement agencies or central guard forces for employment of a quick reaction force in event of forcible entry or other occurrences beyond facility control.

(viii) The security system also shall provide protection against theft or diversion which is facilitated or hidden by tampering with computer systems or electronic records used by licensee.

(B) Facilities which include administrative offices in the same building wherein drugs are handled or stored are not required to comply with the requirements under clause (A)(i), (A)(ii), or (A)(iii) for the office portion of the building; provided, that any door or window connecting the offices with the storage areas of the building meets the requirements of clause (A)(i), (A)(ii), or (A)(iii).

(3) All legend drugs shall be stored at temperatures and under conditions in accordance with manufacturers' requirements, if any, in the labeling of such drugs:

(A) if no storage requirements are established for a legend drug, the drug may be held at a temperature maintained thermostatically between fifty-nine degrees Fahrenheit (59 F) and eighty-six degrees Fahrenheit (86 F) to help ensure that its identity, strength, quality, and purity are not adversely affected;

(B) appropriate manual, electro-mechanical, or electronic temperature and humidity recording equipment, devices, and logs shall be utilized to document proper storage of legend drugs; and

(C) the record keeping requirements under subdivision (6) shall be followed for all incoming and outgoing legend drugs.

(4) Examination of materials shall be as follows:

(A) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated legend drugs or legend drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal damage or tampering that would suggest possible contamination or other damage to the contents.

(B) Each outgoing shipment shall be carefully inspected for identity of the legend drug products and to ensure that there is no delivery of legend drug products that have been damaged in storage or held under improper conditions.

(C) The record keeping requirements under subdivision (6) shall be followed for all incoming and outgoing legend drugs.

(5) Returned, damaged, and outdated prescription drugs shall be handled as follows:

(A) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be held in a quarantine area and physically separated from other legend drugs until they are destroyed or returned to their manufacturer or other agency of origin.

(B) Any legend drugs which have sealed outer or secondary containers that have been opened or used shall be identified as such and shall be quarantined and physically separated from other legend drugs until they are either destroyed or returned to the supplier.

(C) If the conditions or circumstances under which a legend drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be properly destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not circumstances under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(D) The record keeping requirements in subdivision (6) shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated legend drugs.

(6) Record keeping shall be as follows:

(A) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. At a minimum, these records shall include the following information:

(i) The source of the drugs, including the name and principal address and telephone number of the seller or transferor, and the address of the location from which the drugs were shipped.

(ii) The identity and quantity of the drugs received, distributed, or disposed of.

(iii) The dates of receipt and distribution or other disposition of the drugs.

(iv) The identity, principal address, and telephone number of recipients of the drugs.

(B) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials, including the board or its agents for a period of two (2) years following disposition of the drugs.

(C) Records described in this section which are kept at the inspection site, or which can be retrieved immediately by computer or other electronic means, shall be made available for authorized inspection during the retention period. Records kept at a central

location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency, including the board or its agents.

(7) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of legend drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(A) A procedure whereby the oldest approved stock of a legend drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and necessary.

(B) A procedure to be followed for handling recalls and withdrawals of legend drugs. Such procedures shall be adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;

(ii) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health and safety by replacement of existing merchandise with an improved product or new package design.

(C) A procedure to ensure that their facility is prepared to react to crises caused by natural disasters or catastrophic events in a manner which will limit losses through looting, theft, or burglary as much as possible under circumstances existing at the time.

(D) A procedure to ensure that any outdated legend drugs will be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of the outdated legend drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs concerned.

(E) A procedure to be followed in instances wherein thefts or losses of legend drugs are established, which will assure complete reporting of the incident to the board, within ten (10) days of when it is established, and to other law enforcement agencies as required by law.

(8) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug reception, storage, handling, and distribution including a description of their duties and a summary of their qualifications.

(9) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. To this end, distributors shall:

(A) permit the board or its agents and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures to the extent authorized by law; and

(B) wholesale drug distributors who deal in controlled substances shall register with the Indiana controlled substance advisory committee and with the Drug Enforcement Administration and shall comply with all applicable federal, state, and local laws and regulations.

(10) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations which pertain to the reprocessing or salvage of legend drug products.

(Indiana Board of Pharmacy; 856 IAC 3-2-8; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)

End of section.